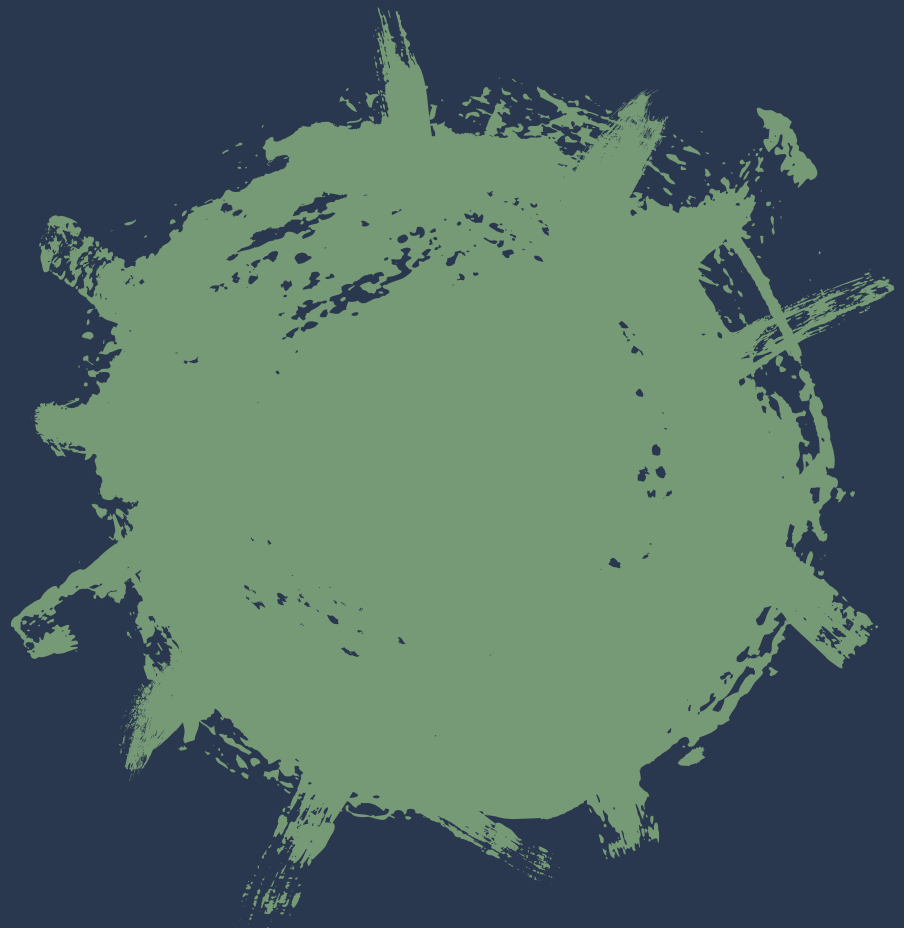




Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH



Medicine & research
Activity report

Activities of the Research Ethics Committees 2020

Summary Report of the Coordination Office
for Human Research (Kofam)

Contents

Foreword	4
----------	---

Summary	5
---------	---

List of ethics committees	6
---------------------------	---

1 Organisation of the ethics committees	8
---	---

2 Activities of the ethics committees	13
---------------------------------------	----

3 Impacts of the Covid-19 pandemic	27
------------------------------------	----

4 Conclusions and outlook	31
---------------------------	----

5 Other supervisory authorities	34
---------------------------------	----

6 Swissethics	36
---------------	----

7 Coordination Office for Human Research (Kofam)	40
--	----

Foreword

In Switzerland, research involving human beings requires authorisation. Under the Human Research Act (HRA), which has been in force since 2014, all human research projects have to be assessed and approved by independent bodies. Responsibility for this essentially lies with seven cantonal ethics committees. In certain cases, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic) or the Federal Office of Public Health (FOPH).

Three types of research projects are subject to mandatory authorisation: clinical trials in humans involving the use of new therapeutic products, surgical methods or other health-related applications; non-clinical studies in humans; and studies involving further use of biological material or health-related personal data. With their assessment and authorisation activities, the cantonal ethics committees make a vital contribution to the protection of persons involved in human research and ensure that research involving humans is beneficial and of high quality.

1 Art. 1 para. 2 let. c HRA

2 Cf. the links given in the Section "List of ethics committees"

This report for 2020 is based on the annual reports prepared by the various ethics committees and other supervisory and approval authorities. It summarises their main activities, thus fulfilling the requirement, specified in the HRA, for the Coordination Office for Human Research (Kofam) to inform the public about human research conducted in Switzerland.¹ The original versions of the individual ethics committees' annual reports are available on their respective websites.²

Kofam would like to thank the cantonal ethics committees for their work and also for their constructive contributions to this report. Thanks are also due to the other supervisory authorities and to the Swiss Association of Research Ethics Committees (Swissethics).

Summary

2020 was an extraordinary year for everyone – including all the actors involved in human research in Switzerland. The activities of the ethics committees were affected in many ways by the Covid-19 pandemic. Firstly, they had to adapt their working processes as a result of the pandemic. At the same time, specific research proposals relating to SARS-CoV-2 and Covid-19 led to an increase in the number of applications to be assessed.

Altogether, 3,033 research projects were submitted in the year under review – around a fifth more than in the previous year. This growth is not only attributable to Covid-related projects; there was also an increase in the number of ordinary research projects. The assessment and authorisation workload increased accordingly. Even so, the legal time limits for the assessment of research projects were complied with across Switzerland. The ethics committees report that priority was given to the assessment of Covid-related research projects so as to facilitate rapid project initiation. According to the committees, however, other research projects were not adversely affected as a result.

Following the declaration of an extraordinary situation, all the ethics committees adapted their working practices in accordance with official recommendations. On account of the general restrictions on social contacts, most meetings, inspections and training and continuing education events were conducted online. For application processing and project assessment, a document circulation procedure was employed in some cases so as to permit time- and location-independent collaboration.

According to the ethics committees, SARS-CoV-2 and Covid-19 are likely to continue exerting a strong influence on human research in the future. They expect to see an increase in both the quantity and quality of Covid-specific research projects. In their view, these developments pose new challenges and make demands on the expertise of committee members. Moreover, as a result of the pandemic, urgent questions which had already in the past formed part of the debate on the development of human research have become even more relevant. These include, for example, medical progress driven by technological advances in the areas of personalised medicine and patient data, as well as new data protection regulations.

The 2020 Annual Report also includes statistics on research project applications submitted and approved. The statistical data from the online submissions portal BASEC was processed in collaboration with the Clinical Trial Unit (CTU) Basel.

List of ethics committees

At the end of 2020, Switzerland had a total of seven (supra-) cantonal ethics committees. This number has thus remained unchanged since the end of 2016. Below, the committees are listed by number of applications received, in ascending order.

EKOS – Ethics Committee of Eastern Switzerland

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
CH-9000 St. Gallen
sekretariat@ekos.ch
www.sg.ch/gesundheit-soziales/gesundheit/gremien.html
Chair: Dr Susanne Driessen

Region covered: cantons of St. Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden

Relevant cantonal regulations

- By-Laws of the Ethics Committee of Eastern Switzerland (EKOS), 10 May 2016

CE-TI – Cantonal Ethics Committee, Ticino

Comitato etico cantonale del Cantone Ticino
c/o Ufficio di sanità
Via Orico 5
CH-6501 Bellinzona
dss-ce@ti.ch
www.ti.ch/ce
Chair: Giovan Maria Zanini

Region covered: canton of Ticino

Relevant cantonal regulations

- By-Laws of the Ethics Committee, 2 July 2002
- Health Promotion and Coordination Act, 18 April 1989
- Ordinance on Committees, Working Groups and Representatives on Bodies Established by the Cantonal Government, 6 May 2008
- Executive Decree Concerning Fees for Administrative Decisions, Controls, Visits and Inspections Provided for by Federal and Cantonal Health Legislation, 16 December 2008

CCER – Cantonal Research Ethics Committee, Geneva

Commission cantonale d'éthique de la recherche
Rue Adrien-Lachenal 8
CH-1207 Genève
ccer@etat.ge.ch
www.ge.ch/lc/ccer

Chair: Professor Bernard Hirschel

Region covered: canton of Geneva

Relevant cantonal regulations

- Regulations for implementation of the Federal Act on Research Involving Human Beings (RaLRH)

KEK-BE – Cantonal Ethics Committee, Bern

Kantonale Ethikkommission Bern
Murtenstrasse 31
CH-3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek

Chair: Professor Christian Seiler

Region covered: canton of Bern and cantons of Fribourg and Valais for German-language submissions

Relevant cantonal regulations

- By-Laws of the Cantonal Research Ethics Committee, Bern (KEK Bern), 21 February 2017
- Ordinance on the Cantonal Research Ethics Committee (KEKV), 20 August 2014
- Administration of Administrative Justice Act (VPRG)
- Intercantonal agreement on the ethics committees responsible for research involving humans: Canton of Fribourg – Canton of Bern, 1 April 2017
- Intercantonal agreement on the ethics committees responsible for research involving humans: Canton of Valais – Canton of Bern, 1 April 2017

CER-VD – Cantonal Research Ethics Committee, Vaud

Commission cantonale d'éthique de la recherche sur l'être humain
Avenue de Chailly 23
CH-1012 Lausanne
secretariat.cer@vd.ch
www.cer-vd.ch

Chair: Professor Dominique Sprumont

Region covered: cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-language submissions

Relevant cantonal regulations

- Public Health Act of the Canton of Vaud, 29 May 1985
- By-Laws of the Cantonal Research Ethics Committee, Vaud, 21 January 2019

EKNZ – Ethics Committee of Northwestern and Central Switzerland

Ethikkommission Nordwest- und Zentralschweiz
Hebelstrasse 53
CH-4056 Basel
eknz@bs.ch
www.eknz.ch

Chair: Professor Christoph Beglinger

Region covered: cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Solothurn, Schwyz, Uri and Zug

Relevant cantonal regulations

- Agreement of 6 September 2013 on the appointment of a joint ethics committee for Northwestern and Central Switzerland (EKNZ)
- By-Laws of the EKNZ, 1 January 2014

KEK-ZH – Cantonal Ethics Committee, Zurich

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
CH-8090 Zürich
info.kek@kek.zh.ch
www.kek.zh.ch

Chair: emeritus Professor Peter Meier-Abt (†27 May 2021)

Region covered: cantons of Zurich, Glarus, Graubünden and Schaffhausen, and the Principality of Liechtenstein

Relevant cantonal regulations

- By-Laws of the Cantonal Ethics Committee, 6 August 2015
- Health Act (GesG), 2 April 2007
- Patients Act, 5 April 2004
- Therapeutic Products Ordinance (HMG), 21 May 2008
- Information and Data Protection Act (IDG), 12 February 2007

1 Organisation of the ethics committees

This section deals with formal aspects of the ethics committees' activities and internal processes, such as the appointment of new committee members or committee composition (by discipline and gender). Information is also given on training/continuing education measures, finances and regulations concerning non-participation in the event of conflicts of interest. All the information provided in this section is based on the individual committees' reports.³

The ethics committees are appointed and overseen by the cantons. In most cases, they are administratively attached to

cantonal health directorates or social services departments, with two committees (Bern and Geneva) being attached to the Cantonal Pharmacist's Office. The committees are overseen by the responsible cantonal government or health department. The Northwestern and Central Switzerland committee is overseen by an intercantonal body, with representatives from the various cantonal health directorates. All the committees operate independently and are not subject to instructions from the supervisory authority.⁴

Composition of the ethics committees

The cantonal ethics committees are "militia" bodies, comprising experts from the fields of medicine, psychology, nursing, pharmacy/pharmacology, biology, biostatistics, ethics and law. In most cases, almost half of the committee members are trained in medicine.

Appointment of members

Committee members are appointed by the cantons – generally by the executive bodies. In the case of the Geneva, Ticino and Zurich ethics committees, the cantonal government is responsible. In Vaud, committee members are appointed by the Head of the Health and Social Services Department; in Eastern Switzerland, they are appointed by the Canton St. Gallen Health Department and the Canton Thurgau Department of Finance and Social Affairs. In Northwestern and Central

Switzerland, appointments are made by the intercantonal supervisory body.

In general, suitable candidates are appointed on the recommendation of the ethics committee concerned (usually the committee chair). In Bern, the Faculty of Medicine is entitled to propose a number of candidates from the medical field, and the Faculty of Human Sciences a candidate from psychology. The other members are appointed by the Health, Social Affairs and Integration Directorate in consultation with the Education Directorate. In the case of supracantonal committees such as the EKNZ, candidates are proposed by the cantons concerned.

Committee members generally serve for a maximum period of four years, except in Geneva and Vaud. Membership of the Geneva committee is not limited, but it has to be formally con-

³ The annual reports and further information are available on the committees' websites or at www.kofam.ch

⁴ Art. 52 para. 1 HRA

Table 1: Composition of ethics committees: disciplines represented (more than one discipline possible per member) and gender balance

	Ethics committees															
	Total		EKOS		CE-TI		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)
Members trained in medicine	98	42.4	5	29.4	8	44.4	16	39.0	12	50.0	15	31.3	10	38.5	32	56.1
Members trained in psychology	16	6.9	1	5.9	0	0.0	2	4.9	2	8.3	5	10.4	2	7.7	4	7.0
Members trained in biology	15	6.5	2	11.8	1	5.6	5	12.2	2	8.3	1	2.1	2	7.7	2	3.5
Members trained in law	20	8.7	2	11.8	2	11.1	3	7.3	3	12.5	4	8.3	3	11.5	3	5.3
Members trained in ethics	15	6.5	1	5.9	2	11.1	2	4.9	1	4.2	5	10.4	2	7.7	2	3.5
Members trained in pharmacy/pharmacology	19	8.2	2	11.8	2	11.1	4	9.8	1	4.2	4	8.3	1	3.8	5	8.8
Members trained in statistics/epidemiology	17	7.4	1	5.9	1	5.6	3	7.3	1	4.2	5	10.4	3	11.5	3	5.3
Members trained in patient advocacy	9	3.9	1	5.9	1	5.6	2	4.9	0	0.0	4	8.3	0	0.0	1	1.8
Members trained in nursing/nursing science	19	8.2	2	11.8	1	5.6	4	9.8	1	4.2	3	6.3	3	11.5	5	8.8
Members trained in other disciplines	3	1.3	0	0.0	0	0.0	0	0.0	1	4.2	2	4.2	0	0.0	0	0.0
Total disciplines represented	231	100	17	7.4	18	7.8	41	17.7	24	10.4	48	20.8	26	11.3	57	24.7
Total members (excluding multiple disciplines) ¹	198	100	13	6.6	17	8.6	36	18.2	22	11.1	38	19.2	26	13.1	46	23.2
Women	90	45.5	6	46.2	5	29.4	22	61.1	6	27.3	21	55.3	12	46.2	18	39.1
Men	108	54.5	7	53.8	12	70.6	14	38.9	16	72.7	17	44.7	14	53.8	28	60.9

¹ Members of individual committees as a proportion of the total number of committee members (row %)

firmed every five years when cantonal elections are held. In Vaud, membership is limited to a five-year term. Reappointment is generally possible, although in Ticino the maximum term is twelve years, except in the case of individuals who, as well as serving as committee members, hold another cantonal position. Members of the Eastern Switzerland and Zurich committees can be reappointed up to the age of 70.

Changes of personnel occurring in 2020 were reported by various ethics committees. The four-year term of EKOS members concluded at the end of May 2020. All members were reappointed except the Thurgau Vice Chair, for which position a new appointment was to be made. Also newly appointed to EKOS was a patient representative. In 2020, three members left the Zurich committee, with two resigning for reasons of age and one leaving for personal reasons. In the elections which took place on 29 April 2020, the Zurich cantonal government appointed six new committee members (four women, two men) to serve from June 2020.

Training for new committee members

Newly appointed committee members are generally required to undergo training on the duties of ethics committees and the fundamentals of the assessment of research projects. For German-speaking new members, a course run by Swissethics was held online on 24 and 25 November 2020. The course content had been developed by Swissethics in 2020 under a mandate from the FOPH.

A course run by the Zurich committee for new members was held on 18 May 2020. This introduction to the work of the ethics committee took the form of a webinar. It covered topics such as legal requirements, assessment of scientific quality, processes and working with BASEC.

Continuing education events

The ethics committees report that, owing to the pandemic, not all continuing education events were able to take place as planned. Whenever possible, these events were held online.

A Swissethics continuing education event for members of ethics committees was held in person on 29 September 2020 in Zurich. The topic was “Artificial intelligence in human research – scientific, legal and ethical challenges”, and the

event was attended by 78 people. The Bern and EKNZ committees report that their annual retreat was cancelled due to the pandemic.

The annual continuing education event for French-speaking committee members was held online on 17 and 24 November 2020 (two half-day sessions). The event run by Swissethics for CER-VD and CCER-GE members was mainly devoted to challenges arising from the pandemic. Another module was concerned with informed consent in children, adolescents and persons lacking capacity. The final module dealt with future changes in the legal foundations in the area of human research (MDR, ClinO-MD). A total of 81 people participated in the event on 17 November, and 72 on 24 November.

At the end of October 2020, the Zurich committee organised a half-day continuing education event for members and staff on the subject of autonomy and general consent. In addition, ten continuing education sessions were held as part of committee meetings. Since November 2020, continuing education events for all members and staff have been held online each month. Two continuing education events were held exclusively for Zurich committee office staff at the Zurich Institute of Forensic Medicine and at the Zurich University Psychiatric Clinic.

Since 2018, committee members’ training and continuing education has been recorded in a central registry by Swissethics – since 2019 with the aid of an online tool. This is designed to document the achievement of specified training and continuing education goals. In 2020, the tool was further developed with the creation of the “Swissethics Library”. Additional training material for self-study has also been made available.

Secretariats

All the ethics committees have an administrative and a scientific secretariat.⁵ The latter, which is required by law, is generally led by a natural scientist, usually a biologist. The Zurich committee also has a legal secretariat and the Geneva committee’s administrative staff includes a legal specialist. The Northwestern and Central Switzerland committee employs students, paid on an hourly basis, to assist as required. The available human resources are shown in Table 2.

Finances

The ethics committees are funded via fees and cantonal contributions. The latter take the form of a fixed annual sum or a deficit guarantee. The overview of income and expenditure for 2020 given in Table 3 includes the reported level of cost coverage. All the figures are derived from the individual committees’ annual reports.

It should be noted that the items included in individual committees’ expenditures vary (e.g. rent for offices/archives, members’ salaries and expenses). Accordingly, expenditures are not fully comparable.

The Ticino committee reports that certain costs (rent, secretariat, travel, training and external experts) are covered by the Health Office budget, and that the Chair’s activities are not remunerated.

The Northwestern and Central Switzerland committee comments as follows on its annual accounts: For 2020, the annual office rental costs were borne by the city of Basel, as the premises are due to be renovated and made earthquake-resistant. For planning reasons, the notice to vacate the premises, already issued for 2020, was suspended and postponed until 2022. In the meantime, the committee was able to continue using the premises free of charge. In addition, the committee reports that salary costs were somewhat higher in 2020 as a result of anniversary bonus payments.

Interests, independence in fulfilment of duties, non-participation

The independence of ethics committees must be assured at all times – from the provision of advice for researchers to the final decision. In the event of a potential conflict of interests, the committee member concerned is required not to participate in decision-making. To ensure transparency, the interests of all committee members are published on the relevant website. Detailed information concerning the implementation of non-participation rules can be found in the committees’ annual reports.

The Ticino committee notes, for example, that newly appointed members are required to disclose any interests to the Cantonal Chancellery. In addition, any committee members who are involved in a project are excluded from discussions and decision-making in this regard. In the case of the

Eastern Switzerland committee, in order to ensure members’ independence, non-participation is required even in cases where there merely appears to be a possibility of partiality.

While the Geneva committee excludes members from decision-making in the event of conflicts of interest, it reserves the right to permit their participation in discussions on the project concerned. To justify this policy, the committee argues that less expertise would be available if more rigid non-participation criteria were applied. In addition, an alternative approach is prescribed if a conflict of interests involves the Chair or Deputy Chairs. In such cases, the project is assessed under the chairship of another committee member. However, as in previous years, the Geneva committee reports that it was not necessary for this procedure to be adopted in 2020.

Under the Bern committee’s non-participation rules, members subject to a conflict of interests must not serve as a reviewer or participate in discussions on the application in question. To prevent influence being exerted indirectly, the person concerned is also required to leave the meeting room.

The Vaud committee makes every effort to exclude committee members from discussions of applications involving a possible conflict of interests, and to deny them access to the dossier concerned. According to the committee, no conflicts of interest arose in 2020.

The Northwestern and Central Switzerland committee notes that its non-participation rules, published on its website, were revised in January 2020. Members abstain from participation in the event of conflicts of interest, and external experts are called in if necessary; this was the case on one occasion in 2020, according to the committee’s report.

In addition to the general regulations on non-participation (last revised on 14 June 2017), which are based on federal jurisprudence concerning the assessment of partiality, the Zurich committee mentions separate rules designed to ensure independence. With regard to the grounds for non-participation, a distinction is made between a subjective perception of partiality and the appearance of partiality. The procedure for non-participation is clearly defined.

⁵ Art. 54 para. 4 HRA

2 Activities of the ethics committees

Table 2: Staffing levels in the scientific and administrative secretariats

Committee	Scientific secretariat	Administrative secretariat	Total no. / percentage
Eastern Switzerland (EKOS)	1 person/80%	1 person/70%	2 persons /150%
Ticino (CE-TI)	2 persons/150%	2 persons/70%	4 persons/220%
Geneva (CCER)	2 persons/140%	3 persons/210% Legal secretariat: 1 person/20%	6 persons/420% (Chair: 50%)
Bern (KEK-BE)	4 persons/355%	3 persons/135%	7 persons/490%
Vaud (CER-VD)	4 persons/280%	4 persons/290%	7 persons/570% (one person works in both secretariats)
Northwestern and Central Switzerland (EKNZ)	4 persons/250%	2 persons/150%	6 persons/400% (plus 3 students paid on an hourly basis)
Zurich (KEK-ZH)	5 persons/360%	4 persons/340% Legal secretariat: 1 person/50%	10 persons/750%

Table 3: Financing of ethics committees

Committee	Fee income / Total income (incl. cantonal contributions)	Expenditure	Reported level of cost coverage
Eastern Switzerland	CHF 343 000/n.a.	CHF 449 000	76%
Ticino	CHF 320 550/n.a.	CHF 314 240	98%
Geneva	CHF 479 632/n.a.	CHF 652 565	73%
Bern	CHF 987 973/n.a.	CHF 966 251	102%
Vaud	CHF 795 000/CHF 1 315 000	CHF 1 421 000	108.1%
Northwestern and Central Switzerland	CHF 1 004 300/CHF 1 134 300	CHF 1 013 535	109.6%
Zurich	CHF 1 493 150/CHF 1 502 550	CHF 1 752 032	86%

In Switzerland, all human research projects have to be assessed by one of the seven (supra-)cantonal ethics committees in accordance with the requirements of the relevant Act and Ordinances.⁶ Central to the committees' activities are the protection of study participants, the scientific quality of the investigation and the benefits of the research. An ethics committee may be responsible for one or more cantons.

Monocentre projects are assessed and approved by a single ethics committee. In the case of multicentre projects, more than one committee is involved in the assessment and approval process: one committee acts as the lead ethics committee, responsible for assessment of the project, while the others serve as the local ethics committees, which examine the local aspects and can also provide the lead ethics committee with information on the project. All the committees operate independently and are not subject to instructions from the supervisory authority.⁷

As well as assessing and approving human research projects, the committees process reports on the safety of study participants and all other reports concerning ongoing projects, assess changes to ongoing projects, and deal with queries concerning responsibility (or otherwise) or relating to the submission of applications and the conduct of projects. In addition, the committees provide general comments and information on notable events in the year under review. They also provide advice for researchers and organise training events.

The information given on the individual committees is derived from their annual reports and is not intended to be exhaustive.

Authorisation procedures

Applicants are required to enter their research project in the online database BASEC (Business Administration System for Ethics Committees). The BASEC data, in turn, serves as the basis for the following tables. For 2020, for the first time, three datasets were generated (rather than two, as in previous years) with the aid of the Clinical Trial Unit (CTU) Basel. As in

the past, the first dataset covers all applications *submitted* and the second all projects *approved*. In the context of the pandemic, the third dataset covers all *Covid-related* projects submitted and approved.

Datasets used for tables

The first dataset, covering all applications *submitted*, was used for the following analyses:

- the total number of applications submitted (Table 4);
- the number of assessment procedures carried out by the ethics committees (Table 5);
- the types of assessment procedure employed by the ethics committees (Table 8).

Underlying the second dataset, which covers all projects *approved*, are the project types (Table 7) and processing times (Table 9).⁸

Each table also includes comparisons with the previous year, in the form of absolute and percentage changes for the parameters in question. Tables based on the first dataset (applications submitted) have a green background, while those based on the second dataset (projects approved) have a blue background. Statistics and charts for the third dataset, covering *Covid-related* projects submitted in 2020, are to be found in a separate report, together with more detailed information on the first and second datasets. Thus, for a more detailed picture, the Statistical Report should be consulted.⁹

Over 3000 research projects submitted

In 2020, a total of 3033 research projects were submitted to the ethics committees for assessment (Tables 4 and 5). This represents an increase of 580 applications (+23.6%) compared to the previous year. This increase is attributable in particular to non-clinical trials involving persons (applications increased by 20% to a total of 1025) and also to research projects involving further use of biological material and/or health-related personal data (applications increased by 29.2% to a total of 1357). The number of research projects approved

⁶ For certain projects, approval must additionally be obtained from the Swiss Agency for Therapeutic Products (Swissmedic) or the Federal Office of Public Health (FOPH). Cf. Section 5 "Other supervisory authorities".

⁷ Art. 52 para. 1 HRA

⁸ The presentation of the ethics committees' decisions is subject to certain restrictions (Table 6): the first dataset used here (applications submitted) covers decisions on applications submitted in 2020 up to the export date (4 April 2021). In contrast, the second dataset (projects approved) only covers decisions on applications approved in 2020, regardless of the year of submission. Applications rejected or withdrawn, or dismissed after an initial assessment, are not included in the second dataset (projects approved), but they are shown separately in Table 6.

⁹ <https://www.kofam.ch/statisticalreport2020>

also increased compared to the previous year, totalling 2447 (+13.3%; Table 7). There was a decrease in the number and proportion of applications rejected (-11; -24.4%) compared to the previous year (Table 6).

Projects submitted: mono- vs multicentre research projects

A distinction needs to be made between mono- and multicentre research projects. Monocentre projects are assessed

and approved by a single ethics committee. In the case of multicentre research projects, however, more than one committee is involved, as the project is to be conducted in a number of regions for which different committees are responsible.

In multicentre studies, the lead role is taken by the ethics committee which is responsible at the site where the coordinating investigator is based. The lead committee seeks

opinions from the other ethics committees concerned and provides a definitive assessment of the research project for all sites.

In 2020, multicentre studies accounted for 8.7% of all applications submitted for approval (here, only the application to the lead ethics committee is counted), while the majority of applications (71.9%) concerned monocentre studies (Table 5).

The total number of assessment procedures carried out by ethics committees – including assessments of multicentre research projects by local committees – is shown in Table 5. Here, it can be seen that a total of 3762 assessment procedures for research projects took place in 2020, an increase of 729 (24.0%) compared to the previous year.

As in previous years, the largest number of applications processed (859) was reported by the Zurich committee. The smallest number of applications processed in 2020, however, was reported by EKOS (209) and not, as in previous years, by the Ticino committee.

Compared to the previous year, the number of applications submitted for multicentre research projects in 2020 increased by 54 (+19.7%), while the number of applications for monocentre projects increased by 526 (+24.1%). In the assessment of applications for multicentre research projects, an average of 2.2 local ethics committees were involved in addition to the lead committee.

Research projects approved by the ethics committees

The authorisations for research projects granted by the various ethics committees are shown in Table 7, broken down by project type and risk category.

The majority of research projects authorised were of two types – projects involving further use of biological material and/or health-related personal data, and non-clinical trial projects involving persons. These two types of research respectively accounted for 45.4% (1110) and 33.9% (829) of all projects authorised. They were followed by clinical trials, which represented 19.5% (476) of the total, with clinical trials of medicinal products accounting for 7.1% (173) and “other clinical trials” 7.4% (180) of all projects authorised.

With regard to authorisations for (non-clinical trial) projects involving persons, the great majority (97.8%; 811) of these projects were in the lowest risk category (A). As regards clinical trials of medicinal products, the majority (73.4%; 127) were in the highest risk category (C). In contrast, 68.1% (75) of the clinical trials of medical devices authorised were in the lowest risk category (A). A similar distribution can be observed in the case of “other clinical trials”, with 150 (83.3%) in risk category A and 30 in risk category B.

Compared to previous years, a further decrease was seen in the number of authorisations granted for clinical trials of medicinal products (-14; -7.5%). The number of clinical trials of medical devices approved was unchanged from the previous year. In contrast, authorisations for non-clinical trial pro-

Table 4: Total number of applications submitted to all ethics committees, by project type

	No. (N)	Percent (%)	Change from previous year (N)	Change from previous year (%)
Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	3033	100	+580	+23.6
Applications for approval of a mono- or multicentre clinical trial	609	20.1	+77	+14.5
Applications for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	1025	33.8	+171	+20.0
Applications for approval of a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	1357	44.7	+307	+29.2
Applications for approval of a mono- or multicentre research project involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	42	1.4	+25	+147.1

Table 5: Number of assessment procedures for applications submitted to ethics committees, by project type

	Total				EKOS		CE-TI		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Percent (col %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)
Number of assessment procedures for applications submitted in 2020	3762	100	+729	+24.0	209	100	216	100	465	100	623	100	661	100	729	100	859	100
Applications for approval of a monocentre research project	2705	71.9	+526	+24.1	97	46.4	133	61.6	343	73.8	438	70.3	506	76.6	537	73.7	651	75.8
Applications submitted to the lead ethics committee for approval of a multicentre research project	328	8.7	+54	+19.7	21	10.0	16	7.4	29	6.2	58	9.3	42	6.4	63	8.6	99	11.5
Applications submitted to local ethics committees for assessment of a multicentre research project	729	19.4	+149	+25.7	91	43.5	67	31.0	93	20.0	127	20.4	113	17.1	129	17.7	109	12.7

Table 6: Total number of applications approved, rejected, withdrawn by the applicant¹ or dismissed, by project type

Number of decisions by ethics committees on applications received for a mono- or multicentre research project (multicentre only as the lead ethics committee)	No. (N)	Percent (col %)		
Number of decisions on a mono- or multicentre clinical trial	494	100		
Approvals	476	96.4		
Rejections	12	2.4		
Dismissals	6	1.2		
Withdrawals ¹	2	–		
Number of decisions on a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	887	100		
Approvals	829	93.5		
Rejections	13	1.5		
Dismissals	45	5.1		
Withdrawals ¹	1	–		
Number of decisions on a mono- or multicentre research project involving further use of biological material and/or health-related personal data (HRO, Chapter 3, incl. research projects approved in accordance with Art. 34 HRA)	1176	100		
Approvals	1110	94.4		
Rejections	8	0.7		
Dismissals	58	4.9		
Withdrawals ¹	0	–		
Number of decisions on a mono- or multicentre research project involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths in accordance with Chapters 4 and 5 HRO	35	100		
Approvals	32	91.4		
Rejections	1	2.9		
Dismissals	2	5.7		
Withdrawals ¹	0	–		
Total number of decisions	2592	100	+299	+13.0
Approvals	2447	94.4	+288	+13.3
Rejections	34	1.3	–11	–24.4
Dismissals	111	4.3	+22	+24.7
Withdrawals ¹	3	–	–14	–82.4

¹ This relates to applications withdrawn by the applicant which have already been subject to an initial decision by an ethics committee. Withdrawn applications for projects not yet assessed are not taken into account.

jects involving persons rose by 99 (+13.6%) compared to the previous year. Likewise, more research projects involving further use of biological material and/or health-related personal data were authorised than in the previous year (+178; +19.1%).

In Table 7, the ethics committees are arranged by the number of applications approved, in ascending order. In 2020, once again, the largest number of applications (645) was approved by the Zurich committee. The lowest number of applications (105), however, was approved by the Eastern Switzerland committee and not, as in 2019, by the Ticino committee.

Types of procedure

Applications submitted for projects in the area of human research are generally assessed using three different types of procedure:

- the regular (plenary) procedure,
- the simplified (three-member subcommittee) procedure, or
- the presidential procedure (decision made by the chair alone).

On the basis of one of these procedures, the applicant will receive a so-called initial decision from the ethics committee.

The type of procedure applied depends on the type of project and the risk category. Table 8 provides an overview of the number of decisions made by the various ethics committees, broken down by type of procedure. The decisions relate exclusively to applications submitted in 2020 for which a decision was made by the date on which the data was exported (4 April 2021).

In 2020, compared to the previous year, the number of initial decisions rose by 546 (+22.8%), which is partly attributable to an increase in the number of applications submitted. As in the previous year, most decisions were made under the simplified procedure (69.3% of the total). Compared to the previous year, the number of decisions increased with all types of procedure – by 295 (+16.9%) for the simplified procedure, by 116 (+33.4%) for the regular procedure, and by 135 (+44.1%) for the presidential procedure.

An exception to this pattern is the Ticino committee, which used the regular procedure for 110 (76.4%) of 144 decisions. In contrast, the Geneva and Bern committees used the simpli-

fied procedure for an above-average number of decisions – 303 (83.7%) and 409 (85.2%) respectively.

As in the previous year, the presidential procedure accounted for around 15.0% of all initial decisions (441 of 2941). The Bern committee, however, used this procedure for only 1.5% of its decisions (7 of 480).

Table 9 shows the median time (number of days) taken by each ethics committee to process applications. Overall, processing times have decreased compared to 2019, although they continue to vary considerably from one committee to another.

Research projects submitted in relation to Covid-19/SARS-CoV-2

Comparison of the (third) BASEC dataset on Covid-19/SARS-CoV-2 (hereafter referred to simply as “Covid” or “Covid-19”) with the first and second datasets shows that, compared to 2019, the number of applications submitted in 2020 increased even if Covid-related applications are not taken into account (+2613 non-Covid-related applications, +6.5%). In addition, there were 420 applications for assessment of Covid-related research projects (13.8% of the total number submitted). More specifically, 39 of these applications (9.3% of all Covid-related submissions) concerned clinical trials, while 187 (44.5%) concerned further use of biological material or health-related personal data, and another 187 (44.5%) concerned non-clinical research involving persons.

Particularly noteworthy is the high proportion of multicentre study designs adopted for certain types of Covid-related projects: 35 (25.1%) of the 139 non-clinical studies involving persons and 31 (22.3%) of the 139 further-use studies approved employed a multicentre design. In addition, in both of these cases, 21 of the projects (i.e. around 15% of all Covid-related applications approved) involved an international multicentre study design. Of the 25 clinical trials approved, no fewer than 7 (28%) were international multicentre research projects. Almost all of the Covid-related projects approved were initiated by investigators independent of industry (industry initiators submitted only 3 of the 25 clinical trials, 2 of the 139 non-clinical studies involving persons and 1 of the 139 further-use projects).

Further and more detailed statistical information on the Covid-related applications submitted can be found in the separately

Table 7: Research projects approved by the ethics committees, broken down by project type and risk category

	Total				EKOS		CE-TI		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Percent (col %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)
Number of mono- or multicentre research projects approved	2447	100	+288	+13.3	105	100	112	100	307	100	370	100	446	100	462	100	645	100
Approvals for clinical trials	476	19.5	-7	-1.4	24	22.9	31	27.7	45	14.7	67	18.1	61	13.7	86	18.6	162	25.1
Approvals for clinical trials of medicinal products	173	7.1	-14	-7.5	13	12.4	16	14.3	10	3.3	24	6.5	23	5.2	31	6.7	56	8.7
Category A	14	0.6	-4	-22.2	0	0.0	3	2.7	4	1.3	2	0.5	0	0.0	2	0.4	3	0.5
Category B	32	1.3	+6	+23.1	1	1.0	2	1.8	1	0.3	5	1.4	5	1.1	11	2.4	7	1.1
Category C	127	5.2	-16	-11.2	12	11.4	11	9.8	5	1.6	17	4.6	18	4.0	18	3.9	46	7.1
Approvals for clinical trials of medical devices	110	4.5	+/-0	-	4	3.8	7	6.3	12	3.9	18	4.9	11	2.5	15	3.2	43	6.7
Category A	75	3.1	-6	-7.4	3	2.9	6	5.4	8	2.6	14	3.8	5	1.1	10	2.2	29	4.5
Category C	35	1.4	+6	+20.7	1	1.0	1	0.9	4	1.3	4	1.1	6	1.3	5	1.1	14	2.2
Approvals for combined clinical trials of medicinal products and medical devices	4	0.2	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	2	0.4	0	0.0	2	0.3
Category A	0	0.0	-1	-100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	1	0.0	+1	-	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2	0	0.0	0	0.0
Category C	3	0.1	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	1	0.2	0	0.0	2	0.3
Approvals for clinical trials of transplant products	6	0.2	+2	+50.0	0	0.0	0	0.0	1	0.3	1	0.3	2	0.4	2	0.4	0	0.0
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	6	0.2	+2	+50.0	0	0.0	0	0.0	1	0.3	1	0.3	2	0.4	2	0.4	0	0.0
Approvals for clinical trials of gene therapy, or of genetically modified or pathogenic organisms	2	0.1	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category B	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	2	0.1	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.3
Approvals for clinical trials of transplantation	1	0.0	+1	-	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0
Category A	0	0.0	+/-0	-	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Category C	1	0.0	+1	-	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0
Approvals for other clinical trials	180	7.4	+4	+2.3	7	6.7	8	7.1	21	6.8	24	6.5	23	5.2	38	8.2	59	9.1
Category A	150	6.1	-7	-4.5	5	4.8	6	5.4	19	6.2	23	6.2	22	4.9	24	5.2	51	7.9
Category B	30	1.2	+11	+57.9	2	1.9	2	1.8	2	0.7	1	0.3	1	0.2	14	3.0	8	1.2
Approvals for research projects involving measures for sampling of biological material or collection of health-related personal data from persons	829	33.9	+99	+13.6	40	38.1	43	38.4	125	40.7	119	32.2	187	41.9	137	29.7	178	27.6
Category A	811	33.1	+102	+14.4	40	38.1	43	38.4	123	40.1	113	30.5	186	41.7	134	29.0	172	26.7
Category B	18	0.7	-3	-14.3	0	0.0	0	0.0	2	0.7	6	1.6	1	0.2	3	0.6	6	0.9
Approvals for research projects involving further use of biological material or health-related personal data	1110	45.4	+178	+19.1	41	39.0	38	33.9	131	42.7	183	49.5	196	43.9	230	49.8	291	45.1
Approvals for research projects involving deceased persons or embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths	32	1.3	+18	+128.6	0	0.0	0	0.0	6	2.0	1	0.3	2	0.4	9	1.9	14	2.2

Table 8: Number of initial decisions by ethics committees, broken down by type of procedure

Details of procedures	Total		Change from previous year (N)		EKOS		CE-TI		CCER		KEK-BE		CER-VD		EKNZ		KEK-ZH	
	No. (N)	Percent (row %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)	No. (N)	Percent (row %)
Plenary committee meetings in 2020	81	100.0	-27	-25.0	3	3.7	0	0.0	7	8.6	23	28.4	24	29.6	12	14.8	12	14.8
Details of procedures	No. (N)	Percent (col %)	Change from previous year (N)	Change from previous year (%)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)	No. (N)	Percent (col %)
Number of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	3033	100	+580	+23.6	118	100	149	100	372	100	496	100	548	100	600	100	750	100
Total no. of initial decisions on applications submitted in 2020 ¹	2941	97.0	+546	+22.8	111	94.1	144	96.6	362	97.3	480	96.8	512	93.4	594	99.0	738	98.4
Decisions made under the regular procedure (Art. 5 OrgO-HRA) ¹	463	15.7	+116	+33.4	18	16.2	110	76.4	20	5.5	64	13.3	78	15.2	62	10.4	111	15.0
Decisions made under the simplified procedure (Art. 6 OrgO-HRA) ¹	2037	69.3	+295	+16.9	71	64.0	25	17.4	303	83.7	409	85.2	362	70.7	430	72.4	437	59.2
Decisions to be made by the chair (Art. 7 OrgO-HRA) ¹	441	15.0	+135	+44.1	22	19.8	9	6.3	39	10.8	7	1.5	72	14.1	102	17.2	190	25.7
Applications submitted in 2020 with no initial decision ¹	92	3.0	+34	+59.0	7	5.9	5	3.4	10	2.7	16	3.2	36	6.6	6	1.0	12	1.6

¹ It should be noted that this includes all decisions up to the date on which the dataset 1 was exported (4 April 2021).

Table 9: Median processing times

Processing times for research projects authorised in 2020 (median number of days)	Total	EKOS	CE-TI	CCER	KEK-BE	CER-VD	EKNZ	KEK-ZH
Time from receipt of application to notification of formal deficiencies for mono- or multicentre research projects ¹	5	1	7	4	2	5	4	7
Time from confirmation of completeness to initial decision for monocentre research projects ^{2,3}	16	4	16	21	18	18	12	17
Time from receipt of application to final decision ("approval") for monocentre research projects ⁴	60	16	52	59	100	92	39	48
Time from confirmation of completeness to initial decision for multicentre research projects (only as lead ethics committee ^{3,5})	20	19	6	23	21	15	21	21
Time from receipt of application to final decision ("approval") for multicentre research projects (only as lead ethics committee ⁴)	84	81	13	119	140	152	78	72

¹ In accordance with Art. 26 para. 1 ClinO or Art. 27 para. 3 ClinO / Art. 16 para. 1 HRO or Art. 17 para. 2 HRO

² In accordance with Art. 26 para. 2 ClinO / Art. 16 para. 2 HRO

³ An initial decision on an application can take the following forms: "approval", "approval subject to conditions" or "not approved with conditions".

⁴ The processing time includes any "clockstops", i.e. the time windows in which the processing time pauses because the applicant has to submit/change something are not deducted.

⁵ In accordance with Art. 27 para. 5 ClinO / Art. 17 para. 4 HRO

published Statistical Report on human research in Switzerland.¹⁰ The impacts of the Covid-19 pandemic on submission and approval practices – and more generally on the modus operandi of the ethics committees – are summarised from the committees' perspective in Section 3 of this report ("Impacts of the Covid-19 pandemic").

Monitoring of research projects

In the conduct of research projects, investigators must fulfil their duties to notify and inform the ethics committees and other supervisory bodies. Significant changes to ongoing projects have to be submitted to the ethics committees for approval. If the safety or health of persons is at risk, the ethics committee responsible may suspend or revoke an authorisation previously granted.

Participation in Swissmedic inspections

The Eastern Switzerland committee is normally represented by its Chair at the initial and final discussions relating to Swissmedic inspections. In 2020, owing to the pandemic, no inspections were carried out in Eastern Switzerland. Likewise, no Swissmedic inspections were carried out in Ticino or Geneva. The Bern committee reports that it attended the final discussions for one inspection. The Vaud committee does not report any participation in inspections, and the Northwestern

and Central Switzerland committee notes that it generally only attends final discussions. The Zurich committee reports that, in 2020, a member of the scientific secretariat attended the final discussions following a Good Clinical Practice (GCP) inspection carried out at a research centre by Swissmedic.

Additional monitoring measures

No additional monitoring measures are reported for 2020 by the Ticino, Eastern Switzerland, Bern or Vaud committee.

The Geneva committee reports that, owing to the pandemic and an absence in the scientific secretariat due to maternity leave, only three of the ten monitoring visits originally planned could take place in the first quarter of 2020. These half-day visits were carried out by the committee chair and a scientific secretary. The annual monitoring of research projects, which involves an online survey of investigators, could not be conducted in 2020. The committee explains that this was due to the higher workload resulting from the increased number of projects submitted.

The Zurich committee carried out an assessment of documentation for selected Heart Surgery Clinic studies. This was undertaken as a complementary measure in response to allegations made against Professor Francesco Maisano, in con-

¹⁰ <https://www.kofam.ch/statisticalreport2020>

sultation with the cantonal health department, the management of USZ and Zurich University, and Swissmedic. The examination of the documents, presented to the Zurich committee within the specified time limit, did not reveal any manifest breach of legal regulations or the general requirements of Good Clinical Practice (GCP).

Ethics committees' comments on the research projects submitted

The following comments, taken from the individual annual reports, represent the views of the ethics committees concerned.

Eastern Switzerland

In the section of the report concerning the number and type of research projects assessed and approved, the Eastern Switzerland committee indicates that 245 applications and queries about responsibility were submitted altogether. The number of applications thus clearly exceeded the usual range (160–200 per year), and 52 queries about responsibility were also dealt with in 2020. One point noted by the committee is the striking increase in further-use research projects (almost 40% more than in the previous year). The number of decisions made by EKOS as the lead ethics committee remained stable (21). However, fewer of these decisions were made under the regular procedure, from which the committee concludes that overall fewer multicentre studies were carried out by industry.

As regards the types of procedure, the committee reports that 18 applications were assessed under the regular, 70 under the simplified and 108 under the presidential procedure. It emphasises that there was a marked increase in decisions made by the Chair in particular: these took the form of an initial decision by the Chair in 22 cases and, in 87 cases, an assessment of local conditions for another committee serving as a lead ethics committee. There were two rejections and no appeals in 2020.

As regards processing times, the committee stresses that all the research projects were assessed well within the legally specified maximum periods.

Ticino

In 2020, almost twice as many research projects in accordance with the Human Research Ordinance (HRO) were submitted to the Ticino committee as in the previous year. Accord-

ing to the committee, this was mainly due to applications for Covid-19 research projects, as the number of clinical studies remained stable.

Geneva

The committee's workload for 2020 is described as sharply increased, with a total of 463 research projects submitted, compared to 343 applications in the previous year. Monocentre projects in particular increased by almost a third. The CCER was involved as a local committee in 91 projects and served as the lead ethics committee for 28 multicentre projects. In Geneva, the number of clinical trials remained stable compared to 2019. However, the number of non-clinical studies involving persons and studies involving further use of biological material and/or health-related personal data increased sharply during the Covid-19 pandemic.

The projects submitted were dealt with by the Geneva committee at a total of 66 meetings. Of these, seven were plenary meetings attended by at least seven members as part of the regular procedure. A smaller group comprising at least three members met as part of the simplified procedure on 29 occasions. Decisions on four applications for further-use projects were made via an e-mail circulation procedure. In addition, 26 extraordinary meetings were held in Geneva to discuss Covid-19 research projects. These were organised by a special sub-committee between 12 March and 18 August 2020. In addition, from 12 March 2020, all of the committee's meetings were held online. Processing times for research projects, from submission to initial decision, have remained stable since 2016, with a median time of 21–24 days. However, the median processing time for newly submitted monocentre projects was reduced by eleven days in 2020. This is explained by the fact that priority was accorded to Covid-19 research projects.

Bern

With regard to the enforcement of authorisation and monitoring procedures for research projects, the Bern committee notes that the number of research applications assessed rose once again in 2020. As well as serving as the lead committee for the assessment of a total of 496 applications, the Bern committee was also involved in a local capacity in 125 cases, with a growing number of applications thus also being seen in this area. In addition, the trend towards more clinical trials also persisted in Bern. The Bern committee received five German-language applications from the canton of Fribourg and

three from the canton of Valais, which was roughly in line with expectations, since bilingual and French-speaking applicants submit their applications to the Vaud committee. Bern also reports an increase in the number of substantial changes to projects. In addition, 22 applications were either dismissed or found not to lie within the responsibility of the committee, and in 195 of a total of 241 determinations of responsibility, the decision was found to lie outside the committee's responsibility.

With regard to procedures and processing times, the Bern committee reports that a total of 62 applications were assessed under the regular procedure at 23 plenary meetings. At weekly committee meetings, 409 applications were assessed under the simplified procedure, and the presidential procedure was employed for 62 applications. Processing times are reported by the committee to be three days from receipt of an application to confirmation of completeness. The median time from confirmation of completeness to initial decision was 18 days for monocentre studies and 20 days for multicentre studies. Overall, processing times for applications have thus been stable over the last two years. The committee additionally comments on the gender balance at plenary meetings, noting that the proportion of female committee members (27%) remains very low in spite of efforts to address this issue.

Vaud

For 2020, the Vaud committee reports a marked increase in applications (+106) compared to the previous year. Research projects were assessed under the regular procedure at 24 meetings. The simplified procedure was employed in 65 cases.

Altogether, 506 monocentre and 152 multicentre studies were assessed by the committee. For the latter, the CER-VD served as the lead committee in 42 cases and was involved as a local committee in 110 cases. The increased workload is mainly attributed to the 88 additional projects submitted in connection with Covid-19. Excluding these specific applications, however, the committee describes the increase as comparable to the previous year, taking this to be an indication of the dynamic development of research in the Lake Geneva region and the neighbouring cantons. The increase in clinical trials is described as moderate, while the increase in research projects in accordance with Chapters 2 and 3 of the HRA is said to be very marked. The increase in master's theses

observed in 2019 did not continue in 2020. With regard to processing times, the committee reports that, thanks to organisational measures, the time required for decisions on new applications was markedly reduced – both for initial and for final decisions.

Northwestern and Central Switzerland

A substantial influence of the pandemic on the number of applications is also noted by the Northwestern and Central Switzerland committee, which reports that the volume of research projects assessed and approved was considerably higher in 2020 than in previous years. However, the increase concerned all categories and is only partly attributable to the increase in applications associated with Covid-19 projects. It is also attributed to the deferral of clinical interventions and operations which, according to the committee, gave various hospitals more time to submit research projects. Covid-related projects were accorded high priority by the committee and were processed within or well within the legally prescribed time limits. This was made possible by the establishment of a special committee responsible for fast-track assessment of Covid-19 projects.

With regard to procedures, a total of 62 applications were assessed under the regular procedure at twelve meetings. With two plenary meetings per month, 428 applications were assessed under the simplified procedure, and 101 under the presidential procedure. In addition, 125 decisions were made as a local and 62 as lead ethics committee. Overall, there were ten rejections, none of which were challenged. The majority of committee meetings were held online.

Zurich

In 2020, the Zurich committee received a total of 855 applications, and an independent assessment was required in 750 cases. The committee was responsible for the assessment of 652 monocentre research projects and served as the lead ethics committee for 98 multicentre projects. An opinion was submitted to another lead ethics committee for a total of 105 projects.

A large proportion of the 750 applications assessed independently concerned clinical trials of medicinal products (74) or medical devices (42); 74 applications came under the heading of "other clinical trials" and three related to clinical trials of genetically modified or pathogenic organisms (in accordance

with Art. 35 ClinO). One application concerned a clinical trial of the transplantation of human organs, tissues and cells (in accordance with Art. 49 and 50 ClinO).

Most of the remaining 556 research projects involved either further use of biological material or data (333 applications) or the collection of health-related personal data and/or sampling of biological material (203). Lastly, for 2020, the committee reports a total of 20 research projects involving deceased persons. For around 400 research projects, the committee examined whether authorisation was required, issuing a declaration of non-responsibility in 356 cases; in the other cases, a standard application and authorisation procedure was required. In addition, a total of 16 initial applications for research projects were rejected by the committee. In most cases, approval was granted when the project was resubmitted following the resolution of serious issues. Applications were dismissed in 24 cases, either because the committee was not responsible or because the application was incomplete.

In summary, the committee notes that the number of applications rose markedly in 2020. With regard to clinical trials, an increase was seen particularly in research projects involving medicinal products, while those involving medical devices decreased, as a result of fewer studies in Category A. However, research in the area of “other clinical trials” increased sharply (+41%). Increases were also observed in the number of multicentre projects for which the committee served as the lead ethics committee, and in the number of projects where further use was made of data or samples.

With regard to median processing times between receipt of application and initial decision, the committee reports a period of 23 calendar days for monocentre and 27 calendar days for multicentre research projects. In both cases, the report notes, this was well within the specified time limit.

Notable events

Notable events such as suspensions, revocations or interruptions of research projects due to notifications are summarised below. In addition, any pending or completed criminal proceedings are reported.

No revocations of authorisations, suspensions of research projects, or criminal proceedings are reported for 2020 by the Ticino, Eastern Switzerland, Vaud or Zurich committee.

The Geneva committee cites the Covid-19 pandemic as a notable event. The committee also emphasises that it continues to receive numerous enquiries as to whether research projects lie outside the scope of the HRA. This subsection of the Geneva committee’s annual report also mentions five applications rejected on account of scientific inadequacies and/or unsuitable methods or a lack of resources. Of these five rejected projects, four were resubmitted.

The Bern committee also reports that one project was rejected on ethical, formal/legal and scientific grounds. In addition, this committee reports two cases of suspension, revocation or interruption due to notifications.

The Vaud committee mentions as a notable event the recruitment of two Vice Chairs serving ad interim: between March and August, this support was provided by two professors so that the committee could deal with the increase in applications for Covid-19 research projects. In addition, from March to July, a special Covid-19 channel was established to permit priority treatment of these dossiers.

The Northwestern and Central Switzerland committee mentions the establishment of a specific subcommittee for so-called Art. 34 applications. According to the committee, this body proved effective in this form and will continue to operate. Because the subcommittee was able to give priority to Covid-19 applications, it is also seen by researchers as a highly efficient solution.

Other activities

Apart from their main activities (assessment of applications for authorisation, monitoring based on notifications from investigators, and determination of responsibility), the ethics committees also provide other services, such as advice for researchers. In addition, they organise events for external participants, thus promoting exchanges with each other, with scientists and with the public and other interested parties.

Appeals procedures

With the exception of the Vaud committee, none of the cantonal ethics committees reports any appeals occurring in 2020. The Zurich committee reports that an appeal lodged by an applicant in 2019 against a rejection issued by the committee had not yet been completed by the end of 2020.

Advice for researchers

Advisory activities are a significant aspect of the ethics committees’ work. In particular, the committees provide support to researchers prior to the submission of applications. This advisory function is an integral part of the committees’ work, covering, for example, advance queries or determination of responsibility. In their reports, the committees emphasise that personal contacts with researchers – prior to the electronic submission of applications via the BASEC portal – make it possible to address numerous concerns and resolve any uncertainties in advance.

Advice may be provided, for instance, on questions concerning the design of a research project. Here, committees may, for example, explain the conditions under which authorisation is or is not required for a project, or researchers may receive information on the requirements for documentation of research projects. Advice may additionally cover topics such as the management of potential conflicts of interest, regulations for clinical trials in emergency situations, and requirements for the informed consent process for study participants. In addition, committees provide advice on questions concerning the steps to be taken after a rejection, or general consent for the use of data and samples. Many committees also take advantage of personal advisory discussions with researchers to clarify divergent positions. Differences of interpretation with regard to a particular research question can then generally be resolved; only in rare cases do they concern ethical issues.

Assessment of research projects in accordance with Art. 11 Stem Cell Research Act (StRA)

No assessments of stem cell research projects are reported by the Eastern Switzerland, Ticino, Geneva or Zurich committees. Under this heading, one application is reported by the Bern committee and two by the Northwestern and Central Switzerland committee.

External events

In 2020, only the Vaud committee organised an event for external participants. The “HRA Lunch” – a series of gatherings held regularly by the committee since 2014 – took place online from March 2020. These events – open to all interested parties – are primarily addressed to scientific staff and researchers. They focus on the discussion of unresolved questions relating to human research. According to the com-

mittee, switching to the online format had a favourable impact on the number of participants, as an average of around 30 people took part in these events compared to 20 in previous years and, in particular, there were more representatives from the Geneva committee and from research centres in Fribourg, Neuchâtel and Valais.

The Zurich committee did not organise any events for external participants in 2020, but it emphasises that existing continuing education and training platforms from external providers were used and committee staff gave 14 invited presentations. Under this heading, the Geneva committee makes reference, as in previous years, to a bulletin published quarterly.

Contacts, dialogue and collaborations

The Eastern Switzerland committee reports extensive contacts with numerous national clinical research institutions. In 2020, according to the committee, these contacts took place almost exclusively online. The committee also cites its collaboration with the St. Gallen CTU, where – as part of the GCP course programme – the “Ethics and the ethics committee” training module is held.

The Geneva committee also reports that a number of collaborative projects were postponed until 2021.

The Vaud committee mentions the participation of its Chair and General Secretary in GCP courses and the General Secretary’s service as a member of the Executive Board of Swiss-ethics.

The Zurich committee reports a variety of regular meetings for the purpose of dialogue and coordination with national and cantonal authorities and institutions. In addition, it mentions the participation of various committee members in projects and working groups.

Other activities of interest to the public

In their annual reports, several of the ethics committees take the opportunity to provide information on other activities of interest to the public. These include, for example, teaching at universities. The Ticino committee mentions the cantonal registry of healthy subjects participating in research projects, which it maintains in cooperation with the Cantonal Pharmacist. In 2020, the registry comprised a total of 189 persons. Of these, 20 took part in two, and 1 in three studies. For clinical

3 Impacts of the Covid-19 pandemic

studies of medicinal products, seven persons were registered. Six patients consulted the advice centre for study participants. Since its establishment in August 2001, it has provided advice for a total of 141 persons.

The Eastern Switzerland committee mentions a conference on “Digitalization and Infectious Diseases” held in January 2020, at which a presentation was given. In addition, a training event was organised for ethics committee members in Zurich in September, and a symposium on “Ethics in Medicine” was held in St. Gallen. The Geneva committee mentions that, as is the case each year, a scientific secretary taught at a workshop for the MAS course on “Management of Clinical Studies” at Geneva University – on this occasion held online. The Vaud committee notes that, over the course of 2020, a series of information items for researchers and research institutions were published on its website. Once again in 2020, the North-western and Central Switzerland committee taught an ethics module as part of the GCP courses held at the Basel CTU.

The Zurich committee reports that, in 2020, six authorisations were granted to the Zurich University Children’s Hospital and one to the University Hospital Zurich for bone marrow donations in accordance with Art. 13 para. 2 Transplantation Act. In addition, the committee received two applications for a temporary authorisation for use and limited commercialisation of a medicinal product. Here, in one case, the committee issued an opinion and, in the other, it determined that there was no need for a temporary authorisation. In addition, a Zurich committee working group prepared recommendations for researchers on the disclosure of interests and the management of conflicts of interest. This is available on the committee’s website.¹¹ For Swissethics, the Zurich committee also prepared recommendations on “Gender equity in research” (available in French/German) and guidance on “Quality assurance, or research subject to approval?”¹²

11 <https://www.zh.ch/de/gesundheit/ethik-humanforschung/dokumente-gesuchseinreichung.html>

12 <https://www.swissethics.ch/themen/positionspapiere-leitfaden>

In reporting on 2020, the ethics committees were requested by the FOPH to prepare a qualitative section concerning the Covid-19 pandemic. In consultation with Swissethics, descriptions were to be given of, for example, general impacts on the committees’ activities and specific effects on submission and assessment practices. In addition, the FOPH is preparing a quantitative evaluation of Covid-related projects and processes on the basis of the BASEC statistics for 2020.¹³

The ethics committees were free to decide what Covid-specific developments to present in their annual reports. Some of the committees prepared a separate report, while others included information on this subject in their annual reports. For guidance, the FOPH compiled a list of questions on how the ethics committees’ activities had been affected by the pandemic. These covered, for example, general challenges and problems arising from the pandemic, as well as scientific or organisational insights which influenced their activities in the course of the pandemic. The committees were also invited to comment on any changes in submission or assessment practices associated with the pandemic.

Eastern Switzerland

In its annual report, the Eastern Switzerland ethics committee provides a detailed account of how its work was affected by the pandemic. The committee notes that the pandemic had a decisive influence, citing for example the replacement of plenary meetings by circulation procedures. Thus, in 2020, the committee held only three plenary meetings for the assessment of 18 applications under the regular procedure. In all other cases, the regular procedure took the form of assessment via a document circulation procedure.

A procedure of this kind, employed by the committee eight times altogether in 2020, is considered legally permissible in exceptional situations and is designed to ensure that operations proceed as smoothly as possible. So far, the committee has not had recourse to online meetings, but it will consider this option if restrictions on social contacts remain in force. With regard to the total of 70 simplified procedures, the committee emphasises that it was still possible for these to be held in person, in an almost unchanged form, with appropriate safety measures being observed. The total of 108 decisions made by the chair were not affected by the pandemic.

13 <https://www.kofam.ch/statisticalreport2020>

As regards Covid-related projects, the committee notes that only applications concerning HRO or further-use projects were received. The applications were submitted primarily by infectious disease departments or the centre for laboratory medicine. In addition, intercantonal and international projects investigated, for example, the intensive care challenges arising from Covid-19. In terms of content, the applications were mainly concerned with coronavirus test development, test evaluation and multicentre health personnel surveys. For the latter, the committee approved for the first time the use of electronic consent (e-consent), in consultation and in collaboration with the St. Gallen cantonal data protection agency. Exchanges with researchers were not, however, affected by the pandemic. In summary, the committee operated effectively in spite of the pandemic and the quality of decisions was not adversely affected.

In the committee’s report, processing times for Covid-related applications are described as considerably shorter. This was due to the committee’s efforts to provide the best possible support for researchers in a difficult pandemic situation through extremely rapid response times. These efforts were particularly successful with regard to the simplified procedure. More generally, however, all research projects were assessed well within the legally specified time limits.

Ticino

The canton of Ticino was disproportionately affected by the first wave of the Covid-19 pandemic. This had a marked impact on the committee’s work, as there was a sharp increase in research activities. Most of the research projects were non-clinical studies involving further use of data or biological material. Applications of this kind could be assessed in writing, using the simplified procedure, and were accorded priority. In addition, the standard seven day period for submission of all required information was set aside. In such cases, the ethics committee’s secretariat contacted researchers directly to resolve any problems. For the approval of applications under the regular procedure, the committee held twelve meetings in 2020. For three of these, the document circulation procedure was used, and two meetings took place by video conference. In general, the Ticino committee notes that the challenges posed by the pandemic were overcome without any major problems.

Geneva

The Geneva committee reports that, as the usual period for the processing of applications proved to be too long, an emergency procedure was introduced – not least because the number of non-Covid-related projects also increased at the same time. Overall, however, the committee is very satisfied that the influx of applications was handled expeditiously without assessment quality being compromised as a result. The committee reports that lessons were learned from the establishment of an ad hoc group which made it possible for applications concerning similar Covid-related research projects to be processed more efficiently but at the same time excluded a number of committee members. Accordingly, the committee concludes that the emergency procedure established is not suitable for use in everyday practice – with only a few exceptions. Covid-related projects are now once again being assessed by the committee using the regular procedure. The committee is however considering whether meetings should in future increasingly be held by video conference.

As a new challenge arising from the pandemic, the committee cites the obtaining of consent for further use of health-related data from study participants. Given the circumstances of Covid-19 infections – such as patient isolation, generally advanced age and restrictions on visits – it is not possible for relatives to be consulted.

With regard to Covid-related research projects, the committee reports that around half of these were applications for further use of medical data for research. For example, according to the committee, large-scale epidemiological studies investigating a representative sample of Geneva's population attracted attention both in Switzerland and abroad. Less satisfactory, however, were contacts and exchanges with researchers and other authorities in the course of the pandemic. The committee encountered criticisms particularly in relation to procedures for further-use research in the case of a number of projects conducted jointly with French researchers. Here, the committee was criticised for the length of the decision-making process.

Bern

The Bern ethics committee sees the impact of the pandemic in the higher total number of applications received. This influenced the working methods both of the scientific secretariat and of the committee – partly because assessments of con-

tent continued unaltered, without any relaxations. The introduction of homeworking created challenges particularly for the scientific secretariat with regard to internal operating procedures. However, communication within the committee or between the office, applicants and external parties was not adversely affected. Meetings held by video conference were initially subject to certain difficulties but now take place in a hybrid form.

With regard to applications for Covid-related research, the committee emphasises that these were processed within a few days using the simplified (circulation) procedure, with assessments being carried out by three selected members. Covid-related applications generally concerned single or repeated collection of blood and saliva and further use of health-related data for the validation of new tests.

In conclusion, the committee notes that the introduction of electronic processes was accelerated by the pandemic. However, despite exceptional efforts, the increase in the total number of applications led to delays in the processing of non-Covid-related applications.

Vaud

The Vaud committee, in a separate report, comments in detail on how its activities and assessment practices were affected or influenced by the pandemic. A challenge, according to the committee, was the complete switchover to homeworking and video conferencing – while at the same time the workload doubled – during the first wave. In addition, given the numerous applications for Covid-related projects, the committee was confronted with problems of realisability and coordination. It was feared, for example, that patients with Covid-19 could become the object of competition between researchers. Moreover, the committee had to remind various research actors that the pandemic does not justify any relaxation of the ethical principles for research, but rather demands compliance with fundamental principles. In general, however, the committee is confident that it was possible for applications to be processed more rapidly than usual without ethical, legal or scientific standards being neglected. The pandemic also led to the introduction of social and technological innovations and ultimately the creation of solutions which, in some cases, will sustainably promote the quality of research. Specifically, the committee cites the example of its experience with video conferences as a viable form of meeting for simplified procedures

and considers itself to be now more experienced in the management of emergency assessments. At the same time, however, it believes that this type of procedure involves a risk of certain persons being excluded, as well as generating additional personnel costs. Emergency assessments should therefore remain the exception.

From this experience, the committee concludes that expedited submission and assessment practices can play a decisive role for research institutions. In the committee's view, however, this approach also underlines the need for institutional capacity outside of the emergency context. It is also noted that existing legislation does not pose any obstacles in connection with the new challenges.

The committee attributes the very large number of applications submitted concerning Covid-related research to the fact that the pandemic was particularly intense within the region for which it is responsible. This, however, also led to more intense contacts with researchers and research institutions.

The committee also notes that a proposal was made, via four circular letters, for the establishment of coordination centres for Covid-related projects. The topics raised included the continuation of projects after the first wave and the expansion of the new project coordination to non-Covid-related research. In the committee's view, these efforts were worthwhile, as institutions, for example, set up working groups so that projects could be better evaluated in advance, thus reducing the number of enquiries submitted to the committee. This gain in quality allows the committee to fulfil its responsibilities more effectively.

The committee also supported a CHUV programme for electronic documentation of patients' consent on a tablet computer. This procedure permits improved coordination and information, as well as greater traceability. According to the committee, this new model was adopted by additional institutions such as the Fribourg Cantonal Hospital (HFR). However, the committee takes a rather critical view of calls from researchers for greater use to be made of Article 34 of the HRA, thus facilitating further use of data or material even without consent. The committee argues that it would be more appropriate to simplify the procedure for obtaining consent from patients or their relatives, for example by introducing verbal, telephone or even post hoc consent.

Northwestern and Central Switzerland

The Northwestern and Central Switzerland committee describes various challenges arising from the pandemic: apart from organisational difficulties, such as homeworking – with deficiencies in personal IT facilities, online contacts as such are cited as an impediment to joint problem-solving. Other challenges reported by the committee are the significantly increased workload and the lack of face-to-face training.

Zurich

In a separate chapter of its annual report, the Zurich committee comments in detail on how the pandemic affected not only its own activities but also research in Switzerland. It first discusses the safety measures defined for the committee's office and for its meetings. From the middle of March 2020, office staff predominantly adopted homeworking, which was retrospectively rated as highly efficient by the committee. As no committee meetings were held between mid-March and mid-July 2020, applications which would normally have required a meeting were assessed via correspondence, in some cases supported by telephone conferences. In the absence of personal contacts, a weekly e-mail newsletter was used to keep all committee members informed about the latest developments. In-person committee meetings were temporarily resumed between mid-July and the beginning of October 2020.

As regards the total number of applications, the committee reports that 129 more were received in 2020 than in the previous year. Research projects concerning SARS-CoV-2 or Covid-19 accounted for just under half of the additional submissions. The applications in question were submitted particularly in April and May 2020, with the largest monthly total (108 applications) being recorded in April. According to the committee, one possible reason for the increase was the greater capacity available in Zurich's hospitals for planning new research projects.

With regard to processing times for Covid-related research projects, the committee was able in most cases to meet its goal of issuing an initial decision within three to seven days after receipt of an application; other research projects were not, however, disadvantaged by the priority assessment of Covid-related projects. In addition, with regard to the type of SARS-CoV-2- and Covid-related applications, the committee expresses its surprise that only a few of the research projects

4 Conclusions and outlook

involved potential treatments for Covid-19. While the committee also expresses its fundamental support for a multicentre approach, this is formulated merely as a recommendation, given that research freedom is a basic right. The committee also points out that, in further-use projects, opportunities for data exchange are scarcely exploited, and a not inconsiderable proportion of these research projects are in mutual competition.

With regard to ethical and scientific standards, the committee emphasises that, in spite of the workload and time pressure, no compromises were made. As a general principle, in connection with SARS-CoV-2-/Covid-related research, the committee notes that it considers any balancing of ethical and scientific criteria on the one hand against speed of assessment and authorisation on the other to be misguided. Research requires unequivocal answers if reliable decisions are to be made in everyday clinical practice and specific measures are to be adopted on this basis. Disregard for scientific and methodological standards opens the door to competing interpretations, making it difficult to obtain valid research results and violating the ethical principles of non-maleficence and equity. As there can be no justification for exposing research participants to risks and burdens with no expectation of benefit, no trade-off arises, in the committee's view, between research standards and time pressure.

With regard to the medium- and long-term impacts of the pandemic, the committee is convinced that research in this field will continue to play an important role in the coming years. According to the committee, the effects of the pandemic on non-Covid-related research in Switzerland will only become apparent from future analyses.

Describing the impacts on the provision of advice for and exchanges with researchers, the committee notes that its safety measures prevented outsiders from visiting its office from March 2020 onwards. Online advice sessions were, however, conducted promptly and effectively.

Finally, the Zurich committee thanks all concerned and draws four conclusions for its future operations: firstly, in view of the efficiency of homeworking, a hybrid solution is to be adopted in the future (remote and office working). Secondly, a digital signature for staff and committee members would simplify the organisation of work and shorten processing times.

Thirdly, while online committee meetings have proved effective, they cannot replace in-person plenary meetings or direct interaction between members. Fourthly, the online format represents a genuine alternative for advisory meetings and internal continuing education events.

This section summarises the ethics committees' assessments of 2020, indicating any difficulties encountered and reflecting on the attainment of their goals. The material taken from the individual committees' reports is not reproduced verbatim and makes no claim to completeness. The impact of the Covid-19 pandemic is also taken into account in the conclusions and outlook presented by the various committees.

Eastern Switzerland

The challenges facing the entire health system as a result of the pandemic in 2020 are also underlined by the Eastern Switzerland ethics committee. Though it was also affected, the committee reports that, for the most part, its activities proceeded smoothly, with the usual quality being maintained. While the workload rose sharply in 2020, this high level represented a return to normal compared to the relatively low number of applications received the previous year. The increase in applications is attributed in particular to multicentre projects, for which EKOS prepared an opinion as a local ethics committee. The biggest change occurring in 2020, according to the committee, was the shift in working methods towards a circulation procedure instead of the plenary meetings normally held for the regular procedure, together with an increase in discussions taking place online via video link.

The committee also makes reference to research projects which, though not concerned with Covid-19, were still affected by pandemic-related restrictions. Research activities were influenced in particular by the fact that participants were not able to attend the study centre in person, or that the entire study setting had to be adapted.

Looking ahead, the committee notes the importance of interdisciplinary exchanges in the ethics committees' work, especially at this time.

From an administrative viewpoint, the committee mentions the submissions portal BASEC and the study portal RAPS (Registry of All Projects in Switzerland). Here, the possibility of automated export is being considered for 2021, so that up-to-date information can be obtained on all projects approved by the ethics committees. The committee also raises the possibility of access via interfaces for external third parties so as to improve the accessibility of BASEC/RAPS data for researchers and other stakeholders, thus also enhancing the ethics committees' general visibility.

A topic of continuing relevance for the Eastern Switzerland committee is the need to address future questions in research ethics. In this connection, reference is made to the challenges arising from increasing digitalisation, artificial intelligence or genetics in clinical and basic research. Also considered challenging is the assessment of clinical studies involving complex design and statistical complexity, as well as the challenges associated with decentralised clinical studies. Here, the committee identifies a need for a more in-depth knowledge of software including deep learning, algorithms, etc. In this respect, the committee takes a positive view of the attention paid to various aspects of digital health as a result of the pandemic and describes the insights gained as significant for the coming years. However, it believes that it will also be essential for committee members to tackle new questions and be offered an expanded programme of continuing education in this area.

Ticino

The Ticino committee notes that, in 2020, the entire health system – including the ethics committee – faced challenges as a result of the Covid-19 pandemic. At the same time, it emphasises that the Federal Act on Research Involving Human Beings was implemented without any particular problems. This conclusion is partly based on compliance with processing times and the lack of complaints from researchers. The processes and procedures – including those for the authorisation of multicentre studies – are described as well-established and effective. According to the committee, this also applies to collaboration with other ethics committees and with federal authorities such as the FOPH and Swissmedic.

Looking ahead, the committee identifies a challenge particularly in the continuous training of committee members, with the complexity of research and technological changes being highlighted in this regard.

Geneva

Reviewing the extraordinary situation of 2020, the Geneva committee concludes that the efficiency of its operations made it possible for (home-based) secretariat staff to deal with all the research applications received without any loss of quality and within the specified time limits. It notes that the use of videoconferences remains important. In addition, collaboration with other ethics committees is seen as a major source of support, although there is still room for further har-

monisation of assessment and authorisation practices. Also considered helpful is the ongoing development of the (already efficient) BASEC portal, particularly with regard to the need for indicators concerning the number of projects or processing times.

The committee defines three main goals for the future: the resumption of follow-up visits, the integration of five new committee members, and the appointment of a patient representative in accordance with the legal requirements to be adopted in 2021. In addition, the committee wishes to plan exchanges with Geneva research actors such as Campus Biotech, the WHO Research Ethics Review Committee and the University insofar as this is permitted by the health situation and workload. Lastly, problems relating to the submission of dossiers are to be addressed, with improvements being proposed which simplify the process for both parties.

Bern

In the sixth year after the introduction of the HRA, the Bern committee considers its activities and procedures in various areas to be well-established. A higher workload due to an increased number of applications is reported in particular for the Chair, for the scientific secretariat and for reviewers of Covid-related applications. With staffing levels, the number of committee members, and the frequency of meetings all remaining unchanged, the committee had to set priorities. However, processing times corresponded to those seen in the two previous years. In the absence of complaints from applicants, the KEK sounding board (established in 2014) did not need to meet in 2020. Also in line with expectations was the small number of submissions received from German-speaking applicants in the cantons of Valais and Fribourg.

Looking ahead, the Bern committee takes up the question of committee members' remuneration, which has so far been based on the 1999 decision of the Cantonal Council (RRB). Because of the pandemic, a compensation review originally scheduled for the end of 2019 did not take place and will now only come into effect in 2021. In addition, the committee's work has been successfully digitalised: remote working and the conduct of meetings in a hybrid format have proved effective and will continue to shape working processes. Whether an increase in staffing levels is required will be decided by the committee according to the future development of the number of submissions.

Vaud

The Vaud committee notes that its membership was reinforced, with a greater female component, in 2020 and expresses its satisfaction at having coped with the increased number of applications, despite the urgency of certain submissions. It also welcomes the constructive dialogue with research institutions and the establishment of the Research Promotion Office (BPR) at Lausanne University Hospital (CHUV) in autumn 2020, even though it is too early to make a detailed assessment of its impact on projects submitted to the committee. There are, however, signs that the creation of this office will make a positive contribution to the smooth processing of research projects from CHUV.

Looking ahead, the committee plans to conduct a review of the organisational measures taken to enable it to continue operating in 2020. This will provide a basis for deciding which innovations should be maintained. With regard to specific research, the committee mentions the increase in further-use projects involving general consent, which proved valuable in connection with CHUV efforts undertaken during the first wave of the pandemic.

In addition, the committee intends to intensify its dialogue with research institutions, which is ultimately to be expanded to include all institutions involved in research. For this purpose, the committee plans to develop a "dashboard" for each institution, so that information and communication can be better structured. The redesign of the committee's website, scheduled for 2020, was however postponed until 2021.

Northwestern and Central Switzerland

In 2020, the Northwestern and Central Switzerland committee once again focused on processing times. The goal of complying with the legally specified time limit for all applications was achieved despite the difficulties caused by the pandemic. The median processing time was comparable with the previous year. The committee also presented a balanced budget, which was due to the increased number of applications received. One critical point made is that, while the BASEC portal is being continuously improved, it is sometimes too slow. Looking ahead, the committee notes that training events and audits are to be resumed, team building is to be promoted, IT infrastructure is to be improved and the new legislation in the area of medical devices is to be implemented.

Zurich

As well as the challenges arising from the pandemic and the higher number of applications compared to the previous year, the Zurich committee draws attention to the renewed increase in multicentre projects. In this connection, reference is made to its role as a lead ethics committee and the confidence placed in it. The committee will continue to attach great importance to the continuing education of committee members and promote contacts and exchanges with partner institutions and organisations in order to optimise human research standards.

Looking ahead, the committee notes that, for reasons of age, the Chair and Vice Chair are to be replaced in June 2021; this also applies to five other committee members. One person will be leaving the committee at his own request. Reference is also made to the revised medical devices legislation, which will have a considerable impact on the committee's activities, as its implementation in some cases will require shorter processing times and additional coordination efforts. Also mentioned is the revision of cantonal law, scheduled for 2021 in Zurich, in connection with the revision of the Therapeutic Products Ordinance (TPA). The planned separate Ordinance on the Cantonal Ethics Committee (KEKV) will provide a legal basis for the charging of fees for services in accordance with Art. 51 para. 2 HRA.

The goals defined by the committee for 2021 are successful management of the challenges associated with the pandemic, continuation of the committee's work under new leadership, and maintenance of the currently effective processing time management. In addition, further optimisation of assessment practice should help to ensure consistency in decision-making, which is to be supported by the development of additional, ethically oriented assessment aids and guidelines.

5 Other supervisory authorities

In this section, the other supervisory authorities report on their activities and draw conclusions concerning the past year.

Swissmedic

Swissmedic – the Swiss Agency for Therapeutic Products (i.e. medicinal products and medical devices) – is based in Bern. The following information on clinical trials with medicinal products and transplant products is taken from its 2020 Annual Report.¹⁴

Clinical trials with medicinal products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Clinical trials of Category B and C may only be carried out in Switzerland if they have been approved by an ethics committee and by Swissmedic. Swissmedic verifies whether the quality and safety of the test product is guaranteed.

Approval for clinical trials with medicinal products is granted by the Clinical Trials (CT) division of Swissmedic.

Swissmedic received 202 applications for new clinical trials of medicinal products during 2020. Of these, it processed 196 and returned the remainder because they were incomplete. A total of 190 clinical trials were approved, 17 of which were associated with Covid-19. Eight of these 17 trials involved first use in humans. Two clinical trials were withdrawn by their sponsors while they were under review. The other applications are currently being processed. The increase in product complexity – and thus in application dossier complexity – that has been observed for several years continued in 2020.

In addition, Swissmedic processed 2,432 other requests or notifications relating to clinical trials (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, end-of-trial reports) as well as 96 reports of suspected unexpected serious adverse reactions (SUSARs).

Clinical trials with transplant products, medicinal products for gene therapy and genetically modified organisms (GVO)

The number of applications for clinical trials of transplant products tripled year-on-year from six to 19. There was a clear

trend towards oncological indications or genetic diseases involving innovative trial medication and complex trial design. Swissmedic also processed 77 (previous year: 84) clinical trial amendments.

GCP and GVP inspections

Swissmedic inspects clinical trials carried out in Switzerland by sponsors, contract research organisations, trial locations, facilities and laboratories. The inspections are carried out on a random basis and assess compliance with the rules of Good Clinical Practice (GCP). They also include the safety and personal rights of trial participants and compliance with scientific quality and integrity criteria.

Pharmacovigilance inspections (Good Vigilance Practice, GVP) are primarily designed to verify compliance with the legally prescribed duty to spontaneously report adverse drug reactions in clinical trials and the implementation of measures associated with urgent drug risks.

In view of the pandemic, regular inspections of clinical trials in hospitals were suspended at the end of March 2020 to avoid placing an additional burden on investigators and trial teams. GCP and GVP inspections of companies were also suspended until the end of June. Models were developed to carry out inspections of sponsors and authorisation holders by live video conferencing. Once inspections resumed in July 2020, they were conducted using a remote procedure, the only exception being one GCP inspection.

The measures to protect the public introduced in connection with the pandemic also affected the implementation and management of approved clinical trials. At the end of March 2020, Swissmedic and Swissethics issued a joint publication setting out the key recommendations for conducting clinical trials during the pandemic.

In the year under review, Swissmedic inspected a total of eight clinical trials. In addition, it conducted seven GVP inspections.

Clinical trials with medical devices

Swissmedic approves and monitors clinical trials of medical devices in humans if the products or intended uses are not yet

CE-certified. While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events, and reports on participant safety.

In 2020, Swissmedic approved 45 first-time applications for clinical trials and 29 variations requiring approval. A total of 101 variations to clinical trials were monitored, as were 91 annual safety reports and 31 safety reports from ongoing trials in Switzerland.

FOPH: Transplantation

Category C clinical trials involving the transplantation of human organs, tissues or cells require authorisation from the Transplantation Section of the FOPH.¹⁵ No new applications were submitted to the FOPH in 2020.

FOPH: Radiological Protection

The FOPH Radiological Protection Division is involved in the procedure for the authorisation of human research projects in special cases. This is always the case when therapeutic products capable of emitting ionising radiation are used in Category C clinical trials. In addition, the Division prepares an opinion for the ethics committee if, in the case of planned concomitant investigations involving radiation sources, the effective dose per person is more than 5 millisieverts (mSv) per year and the interventions in question are not routine nuclear medical examinations using authorised radiopharmaceuticals. This applies both for clinical trials and for all other human research projects.

In 2020, the Radiological Protection Division delivered opinions to Swissmedic in the case of five Category C clinical trials with therapeutic products capable of emitting ionising radiation. In addition, nine opinions were prepared on requested amendments for ongoing clinical trials.

One opinion on concomitant investigations involving radiation sources was prepared by the Radiological Protection Division. In addition, the Division dealt with five enquiries concerning radiopharmaceuticals and three concerning medical devices, which did not necessitate opinions. All opinions were delivered within the specified time limit.

¹⁴ The Annual Report is available on the Swissmedic website:

<https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/aktueller-geschaeftsbericht.html>

¹⁵ Art. 36 para. 1

Transplantation Act and Chapter 3 ClinO

6 Swissethics

The Swissethics association brings together all seven Swiss research ethics committees. As a national umbrella organisation, Swissethics is a central body handling enquiries from researchers, sponsors, CROs and patients, as well as national institutions.¹⁶

Challenge of the pandemic in 2020

In 2020, the Covid-19 pandemic had a major influence on healthcare, health policy and research activities in Switzerland. In response to this extraordinary situation, Swissethics issued two position papers, emphasising inter alia that, even during a pandemic, compliance with ethical and legal standards continues to have top priority, and that all regulatory requirements and safety standards must be observed. In addition, in a paper jointly published in April, Swissethics and Swissmedic addressed the special conditions applicable for the conduct of studies during the pandemic. These include, for example, exceptional arrangements for online visits or the dispatch of study medication, since restrictions on contacts mean that participants are not able to attend the study centre in person. In order to facilitate cooperation between researchers under these difficult conditions, Swissethics decided to publish, as well as a list of all projects authorised, separate lists of all Covid-related projects submitted and authorised.

Collaboration between Swissethics and the FOPH

Among other tasks, Swissethics has a mandate from the FOPH to provide education and training for ethics committee members. As a small number of individuals are appointed to the ethics committees each year, Swissethics over the past year developed a plan for the training of new members. This is designed to ensure that new members are well prepared for their future activities. The training mandate also covers the provision of online material. Thus, members can now access the online Swissethics Library, which offers numerous documents and presentations for self-study in English, French and German.

Swissethics also collaborates with the FOPH in the area of statistics and data analysis. Each year, it makes the BASEC

research data available for analysis by the FOPH. Thanks to this exchange, long-term trends in the development of research can be monitored over the years. In 2020, a distinction was made between Covid- and non-Covid-related applications. In addition, Swissethics received a mandate from the FOPH concerning the analysis of further-use research in Switzerland in accordance with Article 34 HRA. Here, applications for further use of health-related personal data and/or biological material submitted between January and April 2019 were analysed, for example, with regard to data age structure, dataset size, specialty and collection site. This report provides a structured overview at the national level for the first time since the introduction of the HRA.¹⁷

Collaboration between Swissethics and Swissmedic

In 2020, collaboration between Swissethics and Swissmedic involved three main topics: complex clinical trials, decentralised clinical trials, and research involving foodstuffs and dietary supplements. In the case of the latter, it is often not clear which authority is responsible. For this reason, Swissethics in 2020 published a new document designed to facilitate classification.

In complex clinical trials, under a master protocol, provision is made for different study arms, or study medications, which in some cases are only fully defined in the course of implementation. This poses considerable challenges for the authorisation and monitoring of such trials. To provide training on complex clinical studies for ethics committee members, a workshop was held in Bern in February 2020, with the participation of Swissethics, Swissmedic and industry.

Decentralised clinical trials are research projects in which all or certain parts of the study take place outside of the hospital or research centre – for example, in the patient’s home. Here, the use of digital systems is of crucial importance. To raise awareness – among researchers and authorities – of the opportunities and risks associated with digital systems, a Swissmedic Round Table had already been held on this subject in October 2019. The topic was further elaborated by Swissethics in 2020, and the project is to be continued in 2021.

Selected publications 2020

Basic research: guidance for researchers¹⁸

Basic research projects may fall within the scope of the HRA if, for example, coded biological material is used prospectively or retrospectively. The guidance published by Swissethics in July 2020 provides support for scientists conducting basic research by addressing the problems most frequently associated with the submission of such projects to ethics committees: these concern, for example, the handling of incidental findings or the regulation of the storage of biological material.

Including adolescents of childbearing potential in clinical trials or exposure to teratogenic medication: a guide¹⁹

Swissethics and SwissPedNet published a joint position paper on an important topic in adolescent medicine. From an ethical viewpoint, adolescents who take part in studies are in a particularly vulnerable and complex situation. The possibility of pregnancy in minors must be discussed, while also taking into consideration the contraceptive measures to be used (depending on the adolescent’s physical and psychological development) and other issues. The guide offers a practical approach for dealing with the challenges arising in this special situation.

Recommendations on gender equity in research²⁰

Gender equity is an important issue in research: there are significant differences between men and women in many clinical drug trials, as well as in non-clinical trials with persons or in research projects involving further use of health-related personal data and biological material. The recommendations published by Swissethics cover the key steps required for gender equity in research, with ethics committees playing an important role in the assessment of applications. This document was prepared by Dr Peter Kleist, head of the office of the Zurich ethics committee, and made available by Swissethics.

Patient information and comprehensibility

In 2020, the information and consent form templates for participants in clinical and non-clinical trials were completely revised. Wholly new in terms of content and design is the concise version, which no longer consists of an enumeration of the individual points from the informed consent document, focusing instead on the essentials. The concise version was developed by Professor Felix Steiner and his team at the ZHAW School of Applied Linguistics – together with guidance for researchers. The latter explains how informed consent documents can be formulated using simple and comprehensible language.

The question of comprehensibility as an ethical dimension was also raised in a letter from Swissethics to the Swiss Medical Journal (SÄZ).²¹ The Geneva ethics committee initiated a collaboration with the Department of Sociology at Geneva University, where a comprehensive patient survey on informed consent documents was conducted under the direction of Dr Solène Gouilhers.²² This publication and its implications were also discussed within Swissethics and with the FOPH. The OrphAnalytics project (using software to improve comprehensibility of information) was completed on 31 December 2020.

Templates

As a result of the Covid-19 pandemic, which made it necessary in some cases for visits to be carried out online or by telephone, a new addendum to the informed consent document was made available. Also newly developed and published was a template concerning informed consent for further use in a specific research project (in accordance with Art. 28 HRO) of uncoded data and samples collected during a hospital stay and no longer needed for diagnostic purposes. The protocol templates for projects involving further use with and further use

¹⁶ The following sections provide an overview of the activities of Swissethics. For more information, please consult its annual report.

¹⁷ Analysis on the further use of health-related personal data and biological material and the application of Article 34 HRA (https://www.swissethics.ch/assets/swissethics/hfg_evaluation/210121_artikel_34_bericht_final.pdf)

¹⁸ https://www.swissethics.ch/assets/pos_papier_leitfaden/guidance-document-for-researchers_basic-research.pdf

¹⁹ https://www.swissethics.ch/assets/pos_papier_leitfaden/200327_guide_ct_with_adolescentscbp_e.pdf

²⁰ The recommendations are available in French:

https://www.swissethics.ch/assets/pos_papier_leitfaden/201213_recherche-adaptee-au-genre_fr_v1.0.pdf

and in German:

https://www.swissethics.ch/assets/pos_papier_leitfaden/201213_gender-gerechte-forschung_de_v1.0.pdf

²¹ Driessen S, Generalkonsent: Verständlichkeit als ethische Dimension, Bull Med Suisses. 2020;101(41):1306–1307

(<https://saez.ch/article/doi/bms.2020.19271>)

²² Gouilhers S, Saenz Morales A, Amoos M, Riom L, Burton-Jeangros C, *Les documents d’information et de consentement dans la recherche médicale: points de vue des patient.es et exigences institutionnelles*, Rapport de recherche sur la base d’un mandat de la Commission cantonale d’éthique de la recherche de Genève, 2020, Genève: Institut de Recherches Sociologiques, Université de Genève.

without consent (in accordance with Art. 34 HRA) were thoroughly revised. This represents the first application of the results of the analysis of submissions made under Article 34 HRA: the scientific question now has to be formulated more specifically, and data security and processing have to be more precisely defined. Another new requirement is for the size of the dataset (with and without consent) to be clearly specified.

National and international contacts

As a national umbrella organisation, Swissethics serves as a partner for contacts with authorities, industry and other public institutions involved in research. At the European level, contacts and exchanges take place within the European Network of Research Ethics Committees (EUREC), of which Swissethics is a member. Exchanges during the pandemic were particularly intense and effective. In addition, in 2020, Swissethics was once again represented on the SCTO Advisory Board and on the Swiss Biobanking Platform, as well as in the Ethical, Legal and Social Implications (ELSI) advisory group of the Swiss Personalized Health Network (SPHN). Ongoing contacts with the SAMS and unimeduisse are assured by physical proximity in the House of the Academies. In addition, Swissethics participated in discussions with the FOPH and Swissmedic. In 2020, contacts with industry were intensified and were highly constructive, as the pandemic called for particularly close coordination between industry and authorities. In March 2020, Swissethics together with Swissmedic took part in the annual SCTO Round Table event.

Contacts with the Swiss Group for Clinical Cancer Research (SAKK), which in 2019 and 2020 were shaped by the development of a large registry database, were determined at the end of 2020 by the consequences of the SAKK's financial position. Here, the ethics committees wish to fulfil their duty to ensure that the protection of study participants continues to be guaranteed even if studies have to be terminated or suspended for financial reasons.

BASEC, RAPS and website

The most important innovation on the BASEC portal, launched in June 2020, was the new submission form introduced for optional preliminary assessment of registries and/or biobanks by the ethics committees. This represents the practical implementation of the guidance on registries in human research

published in 2019. Ethical evaluations by an ethics committee or opinions on research projects conducted abroad may also be obtained. Maintaining the BASEC portal and informing the public about research projects authorised in Switzerland are core responsibilities of Swissethics. On average, the database was consulted 627 times per month in 2020 (158 page views per day).

The Registry of All Projects in Switzerland (RAPS) is being further expanded. An important decision in this regard was taken by the Board in December 2020, namely the establishment of additional functionality to enable requests from external third parties to be processed more easily. The website continues to be widely used and, at the national level, is the site most frequently visited by researchers in relation to regulatory matters and questions concerning research ethics and the conduct of clinical studies and human research projects. Overall, in 2020, Swissethics recorded an average of 22,918 website visits per month, or 3,935 page views per day.

GCP course recognition

The recognition of GCP courses by Swissethics was continued. One course was newly recognised at sponsor level, and five enquiries were received concerning GCP refresher courses. There is no official recognition for refresher courses, as the submission of these courses to Swissethics is optional. In 2020, GCP course providers also switched to online events in some cases.

Annual accounts for 2020

The basic financing of the Swissethics office and the BASEC portal in 2020 was provided by the cantons. This was supplemented by the remuneration received by Swissethics from the FOPH in connection with the mandates for training and continuing education, BASEC statistics and the project on the analysis of further use in accordance with Article 34 HRA. Invoices to the FOPH totalled CHF 105,124 in 2020. The total budget amounts to CHF 636,000.

Conclusions and outlook

2020 was a year marked by the extensive challenges arising from the Covid-19 pandemic. It was a year in which the ethics committees and Swissethics were repeatedly required to respond rapidly so as to meet changing demands. On the one

hand, there was a desire to support and in no way impede research activities, as reflected by the very short average processing times. At the same time, no compromises of any kind were to be made in areas affecting patient safety or involving other ethical standards.

A number of challenges remain – for example, with regard to the implementation at the European and Swiss level of the Medical Device Regulation, whose entry into force was postponed until May 2021. On the basis of the new Ordinance on Clinical Trials with Medical Devices (ClinO-MD) and regulatory changes, Swissethics plans to collaborate closely with Swissmedic on the national decision letter. This work was resumed in January 2021.

The BASEC portal continues to be regularly updated: mention should be made of the plans to make it easier for external third parties to benefit from BASEC and RAPS. In addition, increased transparency is promoted by the new ClinO-MD, particularly with regard to the publication of results. These results could be submitted via BASEC and would then be automatically transferred to the Swiss National Clinical Trials Portal (SNCTP). This procedure appears to be appropriate since the SNCTP currently already receives the most important publication dataset from BASEC. The two processes mentioned (BASEC/RAPS and BASEC/SNCTP) will require IT investments in 2021. Website maintenance will also continue unchanged in the coming year. Also remaining on the agenda for 2021 are major harmonisation-related activities such as the development of position papers or templates.

7 Coordination Office for Human Research (Kofam)

The Coordination Office for Human Research (Kofam) is operated by the Federal Office of Public Health (FOPH). As well as coordinating the supervisory authorities' activities, it provides information both for the public and for researchers. This section summarises the activities of Kofam in 2020.

Coordination of supervisory authorities and public information

Discussion meetings

In 2020, due to the epidemiological situation, three of Kofam's four discussion meetings with representatives of the supervisory authorities were held online. The fourth meeting took place in person at the beginning of the year (February 2020); this was attended by the Chairs and representatives of the scientific secretariats of the cantonal ethics committees, as well as representatives of Swissethics, Swissmedic and the FOPH Radiological Protection Division. Two further discussion meetings were held online during the first and at the start of the second wave of the pandemic.

The general discussion meeting, previously held once a year, was cancelled in November 2020 as a result of the pandemic, with an additional (smaller) discussion meeting being held online. Accordingly, no overarching theme was selected, in contrast to the format usually adopted for the general discussion meeting. Instead, the authorities participating once again took the opportunity to discuss and coordinate their enforcement-related activities.

Summary of the supervisory authorities' annual reports and statistical overview of research projects submitted

Each year since 2014, Kofam has summarised the reports on the activities of the cantonal ethics committees and other supervisory authorities in an overall annual report. The present report is the seventh annual report of this type. It also incorporates key data from the ethics committees on research projects submitted and approved.

Since 2019, in addition to the annual report, a statistical evaluation has been published each year: "Human Research in

Switzerland – Descriptive statistics on research covered by the Human Research Act (HRA)".²³ The statistical report provides quantitative information on various aspects of the human research projects submitted and approved in the year under review. These include the therapeutic area, the ethics committees' response times, the study design (national or international), and the project initiator (industry or academic). For 2020, in view of the pandemic and its direct effects on human research, applications and projects relating to a specific disease or pathogen (i.e. Covid-19 or SARS-CoV-2) are separately reported for the first time. This additional analysis – like the figures for the aspects analysed each year – is based on the BASEC database and was prepared in collaboration with Swissethics and the Clinical Trial Unit (CTU) Basel.

Kofam website

The Kofam website²⁴ provides information on human research in Switzerland both for the general public and for researchers. The website is widely used, with an average of 506 page views per day in 2020. This corresponds to over 19,500 page views per month – an increase of almost 27% compared to the previous year. Overall, the website was consulted by over 60,500 unique visitors in 2020 – 56% more than in the previous year; this rise may be attributable to the increased need for information associated with the pandemic.

Half (around 52%) of the users are from Switzerland, with most of the remainder coming from Europe. The most frequently visited website sections are the Swiss National Clinical Trials Portal (SNCTP; 75% of page views) and the online wizard for categorising human research projects (Categoriser; 10% of page views). In total, almost 26,000 queries were carried out in 2020.

Via its inbox²⁵ Kofam responded to numerous enquiries from researchers in 2020 concerning the scope of the Human Research Act and the Epidemics Act in the context of the pandemic. Members of the public, for their part, were particularly interested in receiving information on participation in Covid-related research projects. In line with its coordination function, Kofam also forwarded numerous queries to the body responsible – in many cases, the appropriate ethics committee.

Swiss National Clinical Trials Portal (SNCTP)

Every clinical trial authorised in Switzerland must be entered in a registry and thus made public before it is conducted. This involves the trial registration data being entered (in accordance with international GCP standards) in a WHO Primary Registry or on clinicaltrials.gov. Under Swiss law, further information is to be recorded in BASEC in one of Switzerland's national languages and in a generally comprehensible form. Via the Primary Registry number, the Primary Registry entry is linked to the supplementary information from BASEC and automatically published on the Swiss National Clinical Trials Portal (SNCTP).

The SNCTP, on which every clinical trial authorised in Switzerland is published, is run by Kofam. This portal was updated in 2020 (Release 3.0). In particular, the interfaces with the cantonal submissions portal BASEC and the WHO database were improved, and new filter and display functions were introduced.

Thus, users can now filter search results by specific groups (children, adolescents, healthy persons) and hide trials which are no longer open for participation. Accordingly, the information shown for individual trials now also includes the completion date (if available) and the date of authorisation by the relevant ethics committee. Also displayed is a summary of trial results (if available), with a link to a publication or publication plan. All these innovations are in accordance with the legal requirements for transparency and quality of human research and reflect the needs of SNCTP users.

Most enquiries submitted via the SNCTP inbox concern an existing entry or, more generally, the registration of a research project. Increasingly rare, in contrast, are enquiries concerning the registration of trials launched before the introduction of BASEC.

Other law enforcement-related activities

Studies on the enforcement of Art. 34 HRA

Further use for research purposes of (already collected) health-related personal data and (already sampled) biological material plays a major role in human research and, in principle, requires the consent of the persons concerned. However, for

certain strictly defined cases, Article 34 HRA specifies that, by way of exception, further use may be made of data or biological material for research purposes without the consent of the persons concerned. In these cases, a so-called consent substitute is issued by the responsible ethics committee. But, as shown by the evaluation of human research regulations between 2017 and 2019, applications for the use of Article 34 HRA account for around half of all further-use submissions and thus do not, at least in quantitative terms, represent an exception. Against this background, two studies were commissioned with the aim of obtaining more information on the use of Article 34 HRA.

Firstly, Swissethics carried out a structured analysis of applications for further use of data and biological material in accordance with Article 34 HRA and then compared these with applications for research projects involving further use (with consent). The aim was to gain an overview of the type of applications based on Art. 34, and to find out more about how applicants interpret the provisions of Art. 34 and how ethics committees handle these applications as part of their enforcement activities. More detailed information on the aims, methods and results of this study are to be found in a separate report (in German) available online.²⁶

Secondly, the economic consultants BSS interviewed representatives of the ethics committees to determine how they handle applications for the use of Article 34 HRA. Further details of this study on the enforcement of Article 34 HRA can also be found in a separate report (in German) available online.²⁷

Comprehensibility of informed consent documents

Since 2019, with the aim of enhancing the comprehensibility of informed consent documents for study participants, the Institute of Language Competence at the ZHAW School of Applied Linguistics, in collaboration with the ethics committees, has been revising guidance on informed consent from a linguistic perspective. The Swissethics template for drafting information for participants in studies involving humans in accordance with the HRA/ClinO now begins with a concise

²³ <https://www.kofam.ch/statisticalreport2020>

²⁴ <https://www.kofam.ch>

²⁵ Queries should be sent to: kofam@bag.admin.ch

²⁶ Analyse zur Weiterverwendung von gesundheitsbezogenen Personendaten und biologischem Material sowie Anwendung von Art. 34 HFG; for an English summary of the report cf. Link

²⁷ Befragung der Ethikkommissionen zur Anwendung von Art. 34 HFG; for an English summary of the report cf. Link

version, which summarises the essential points for participants and is formulated in a comprehensible manner, in accordance with the participants' linguistic capacity. This concise version has been in use since the beginning of July 2021, and its effectiveness is currently being evaluated. In addition, guidance is being developed for researchers, to help them formulate informed consent documents in such a way that they are comprehensible for patients.

Conclusions and outlook

In 2020, responsibility for the operation of Kofam was assigned to the management of the Human Research Section of the FOPH. At the same time, Kofam adapted its coordination activities to pandemic conditions, conducting discussion meetings with the supervisory authorities online. Various projects – such as the BASEC analysis of Article 34 applications entrusted to Swissethics – were completed in spite of the adverse conditions. Other activities – such as the finalisation, with Swissethics, of the plan for education and training of committee members – had to be placed on the back burner as a result of the pandemic.

Thus, also suspended – for brief or more extended periods – was work on the revision of the Human Research Ordinances, in the course of which, for example, the future tasks of Kofam are to be reviewed and redefined. This revision work is to be resumed and completed as soon as is permitted by the epidemiological situation and the associated availability of capacity within the FOPH. In any event, in order to coordinate the activities of the ethics committees and other human research actors, Kofam will continue to employ the established meeting formats – either online or hybrid, depending on the epidemiological conditions. In addition, according to available capacity, the completion and implementation of the education and training plan for committee members is to be pursued with Swissethics. Kofam will also continue to endeavour to meet the needs of the general public and researchers for information on human research in Switzerland.

Finally, Kofam would like to take this opportunity to express its gratitude for the tireless commitment exhibited – also during the pandemic – by the ethics committees, Swissethics, Swissmedic, and the FOPH and FOEN enforcement authorities.

PUBLICATION DETAILS

Publisher

Federal Office of Public Health (FOPH)
Division of Biomedicine
Coordination Office for Human Research (Kofam)

Contact

Coordination Office for Human Research (Kofam)
c/o Federal Office of Public Health (FOPH)
P.O. Box
3003 Bern
kofam@bag.admin.ch
www.bag.admin.ch/human-research

Publication date

December 2021

Digital language versions

This publication is available as PDF in German, French, Italian or English at www.kofam.ch/en/downloads.